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Expert Opinion

Brexit – What are the potential consequences for pharma patents and SPCs?

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ABSTRACT

Brexit raises a number of difficult questions with regard to intellectual property rights in a post-Brexit world, particularly for UK based pharma companies. Whilst the position with regard to the current European patent system is unchanged, the fate of the unitary patent and the unified patent court remains uncertain. Of more immediate concern is the possible future position with respect to supplementary patent certificates. Should the UK fail to reach an agreement with the EU with respect to marketing authorisations for new pharmaceuticals then there is a real possibility that UK based pharma companies may find themselves in a position where they are unable to obtain EU-wide SPC protection.

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INTRODUCTION

On 23 June 2016 the people of the UK voted (by a slim majority) in favour of leaving the European Union. Since that time the government has suggested that it intends to pursue a so-called “hard” Brexit - a clean break from the EU. The primary intention of this clean break is to put the UK in a position wherein it is no longer bound by the laws of the EU, and no longer falls within the jurisdiction of the Court of Justice of the European Union (CJEU) (GovUK 2017a).

So what could a clean break from the EU mean for UK and EU intellectual property rights, particularly for the pharmaceutical industry?

The following takes a brief look at the potential impact upon patents and supplementary protection certificates following Brexit. To prevent this opinion piece from becoming the length of an international

treaty, the effect of Brexit on other IP rights (designs, copyright, trademarks) and issues associated with the use of IP rights (such as competition law, exhaustion of rights, etc.) will not be discussed in this article.

PATENTS

The current system for obtaining patent protection in the UK and in the EU will remain the same. This is because the European Patent Office (EPO), which examines and grants European patents, is not an EU institution and does not fall within the jurisdiction of the CJEU.

In the current European patent system, a European patent application is examined centrally by the EPO. Once the EPO is satisfied that the requirements for grant have been met, it grants a European patent. The European patent is then validated in as many of the contracting states, extension states and validation

states (EPO 2017a) as desired, at which point it becomes a bundle of individual national patents (one granted national patent for each validated state).

In an attempt to simplify this process, a new system has been developed - the Unitary Patent (UP) and the Unified Patent Court (UPC). The aim of this system is to (eventually) make it possible to obtain patent protection in up to 26 EU Member States through a single pan-European patent (rather than a plurality of national patents) and litigate centrally (rather than litigate each national patent in each separate jurisdiction) (EPO 2017b).

The UP/UPC therefore may be an attractive option to the pharma industry, as it would allow for reduced litigation costs and reduced patent renewal fees. Of course, the down side to the holder of a UP vis-à-vis the current European patent system would be the risks associated with central revocation of a UP (i.e. significant loss of EU patent coverage in a single action) coupled with the fact that the UPC would be a new and therefore untested court system.

The UP and the UPC will be governed by EU law (under “the Agreement on a Unified Patent Court” (UPCA) (UPC 2017a) and the CJEU will have jurisdictional primacy. For the UPCA to come into force, the UPCA must be signed and ratified by 13 EU Member States, including France, Germany and the UK (UPC 2017b)

Prior to the Brexit vote, ratification by the UK would have been little more than a formality. However, following the Brexit vote it seemed that the UP and UPC could quite possibly be dead in the water.

It was therefore rather surprising that in November 2016 the UK government announced its intention to ratify the UPCA. This appeared to be at odds with the government’s current political position; on the one hand the government wanted to bring the UPCA (i.e. EU law) into force in the UK post-Brexit, and on the other hand wanted to distance a post-Brexit UK from EU laws. This conflict is therefore likely to cause some significant problems in the future.

However, at present the situation is that the UPCA will be ratified and brought into force in the UK in the not too distant future – the entry into force date is estimated to be sometime in early 2018 (however, this

date could be further delayed due to a recent legal challenge to the UPC in Germany) (IPKat 2017). But what happens when the UK leaves the EU in 2019?

There will be transitional period in place for an unspecified period of time (GovUK 2017b), but no specifics of the transitional arrangements have yet been provided. Without the specifics of those arrangements it is not possible to say what may or may not happen to the UP/UPC system immediately after the UK leaves the EU. It is also too early to say whether the UK would continue to participate in the UP/UPC after the conclusion of Brexit.

This also begs the question of what might happen to the proposed London based central division of the UPC, which will hear cases relating to chemistry, including pharmaceuticals and the life sciences. In a recent press conference (EC 2017) Michael Barnier, when questioned over the possible relocation of the London based central division of the UPC, stated that “we are looking into it”. The fate of the London based central division of the UPC would therefore appear uncertain.

SUPPLEMENTARY PROTECTION CERTIFICATES (SPCS)

SPCs are an important additional form of protection for the pharmaceutical industry. They can extend the normal 20 year term of patents relating to medicinal or plant protection products by up to 5 years (5½ years for paediatric medicines). That patent term extension is to compensate for the time taken to obtain authorisation to place the relevant product on the market.

SPCs are a national IP right, not a pan-EU IP right; each national SPC must be registered in each individual EU member state. In order to obtain an SPC in an EU member state, it is necessary to hold both a valid national patent in that EU member state that protects the active ingredient and a valid marketing authorisation (MA) to place the active ingredient on the market of that EU member state as a pharmaceutical or plant protection product (GovUK 2017c). In the UK, the bodies that may grant MAs are primarily the Medicines and Healthcare Products Regulatory Authority (MHRA) and the EMA, a decentralised agency of the EU which evaluates

medicines throughout their life cycle and issues MAs for approved medicines.

The legal basis for SPCs in the UK is derived from EU regulations (EC 1996, 2009) therefore upon leaving the EU those laws will cease to apply to the UK. However, the “Great Repeal Bill” is intended to convert directly-applicable EU laws (i.e. EU regulations) into UK law (GovUK 2017a). As such, it would seem that there may not be a hiatus in the protection provided by current SPCs or in obtaining new SPCs within the UK, but again this is a rather uncertain area that will require clarifying in due course.

Perhaps more worryingly for pharmaceutical companies based solely in the UK (e.g. SMEs or overseas pharma companies with their EU base located in the UK) is the position in which they might find themselves in a post-Brexit UK when looking to obtain EU-wide SPC protection.

Pre-Brexit, the most efficient and hence most commonly used procedure for obtaining an SPC in several EU member states was to obtain a MA from the EMA, and use that MA to register an SPC in each of the EU member states in which the pharmaceutical company has a valid national patent. This was a reasonably streamlined process.

However, following Brexit, the UK’s membership of the EMA is at risk. There is no provision in the law regulating the EMA (EC 2004) for participation of the EMA with non-EU states. As such, any future UK membership of the EMA (or perhaps even an equivalent reciprocal agreement between the UK and the EMA) will be dependent on Brexit negotiations. So what effect could this have on current and future MAs issued by the EMA?

A recent EU Commission and EMA Notice (EMA 2017a) would appear to be a warning shot to UK based companies who currently hold an MA issued by the EMA. That notice reiterates certain residency and activity requirements for MA holders (EMA 2017b):

- EU law requires that marketing authorisation holders are established in the EU or EEA; and
- Some activities must be performed in the EU or EEA, related for example to pharmacovigilance, batch release, etc.

Furthermore, that notice expressly states that “marketing authorisation holders may be required to adapt processes and to consider changes to the terms of the marketing authorisation in order to ensure its continuous validity and exploitation, once the United Kingdom has left the Union”. A subsequent notice from the Commission and EMA (EMA 2017c) states that MA holders established in the UK “will normally need to transfer [their] marketing authorisation to a holder established in the Union (EEA)”. That subsequent notice also sets out further activity requirements that may have to be transferred to the EEA.

The reference to “continuous validity and exploitation” of MAs may be an implicit warning to companies based in the UK that, unless the above requirements are met, the legal validity of their EMA issued MA may be called into question. If this is correct, then that would also seem to imply that the legal validity of any granted SPCs based thereupon might be called into question (considering that the SPC may no longer be based on a valid MA).

Those notices from the Commission and EMA would therefore seem to be suggesting that UK based pharma companies may have to consider either collaborating/merging with EU based pharma companies, or relocating at least some of their commercial residence and R&D activities to an EEA member state if they wish to maintain their current MAs issued by the EMA and obtain further MAs from the EMA. That, of course, would be detrimental to pharmaceutical R&D in the UK, thereby reiterating the need for the UK to promptly strike a deal with the EU on this front.

Following this theme, in the EU/EEA it is currently a compulsory requirement for pharma companies to obtain an MA from the EMA for the following (EMA 2007):

- new active ingredients indicated for HIV, cancer, diabetes, neuro-degenerative diseases, autoimmune dysfunctions and viral diseases;
- medicines derived from biotechnology processes, such as genetic engineering;
- advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;
- orphan medicines (medicines for rare diseases); and

- veterinary medicines for use as growth or yield enhancers.

This raises the question of how a UK based company developing any of the above medicines would be able to obtain marketing authorisation for its newly developed medicine in the EU/EEA post-Brexit (bar altering its commercial residency and activities). If it is not possible for such companies to obtain an MA in the EU/EEA then (notwithstanding the impact which that alone may have on such companies) the implication may be that SPC protection may no longer be available to those companies unless they “set up shop” in the EU/EEA.

As a final passing comment regarding SPCs, the EU Commission is currently looking into the possibility of having a single pan-EU SPC based on a UP. This is still in the embryonic stages of its life cycle, but hopefully the Commission will publish a report on its findings in the not too distant future.

CONCLUSIONS

The current European patent system will continue to function as it has done for the past 40 years, and patents will continue to be examined and granted in the usual manner with no interruption to service.

With regard to the immediate fate of the UP/UPC, it is really too soon to tell what is going to happen post-Brexit. The “best-case scenario” would be a fully functional UP/UPC system that is up and running by spring 2018. The “worst-case scenario” would be the UP/UPC system being scrapped in its entirety. The likely outcome could quite possibly fall somewhere in between the two extremes.

The situation with regard to SPCs looks to be somewhat more challenging and complex, particularly with regard to the implications of the UK no longer being a member of the EMA. Again, it is really too soon to tell what is going to happen post-Brexit. However, one may speculate that if the situation regarding MAs is not sorted out quickly then we could quite possibly see a number of existing UK pharma companies move their base of operations to the EU, and in the future pharma companies looking to set up in Europe may favour an EU member state over the UK. Both of those hypothetical situations

would be detrimental to pharmaceutical R&D in the UK.

A prudent and rather straightforward solution to all of the above issues may be for the UK to agree to remain bound by EU law for intellectual property matters. The current political climate, however, would seem to preclude such a scenario.

So, in conclusion, it would seem that a “clean break” from the EU may (somewhat unsurprisingly) cause more legal issues than it may solve for pharmaceutical related IP. Given that Brexit has produced a legal quagmire in the UK, the Authors would be rather surprised if these specific issues were given priority during the Brexit negotiations or debated in parliament any time soon. We could be waiting a while for much needed answers, but hopefully not too long.

CONFLICT OF INTEREST

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