IP Impact of Brexit

How will the Brexit affect your Supplementary Protection Certificates?
Introduction

On 23 June 2016, a referendum was held in the UK concerning the question of whether the UK’s membership of the EU should be continued or terminated. The outcome was a result of 52% in favour of leaving the EU, and 48% in favour of remaining. In order for the UK to leave the EU, the UK will first have to make a formal request to leave under Article 50 of the Lisbon Treaty. This will then start a 2-year period during which the terms of the UK’s relationship with the EU after leaving will be defined.

Following the UK’s recent decision to leave the EU, companies are asking themselves how this impacts their business and how it will affect their IP rights. Whilst the Brexit itself will not happen soon, it is important to already start to think about the possible implications, and to start to make preparations.

Supplementary Protection Certificates

The extension of patent-protection of certain pharmaceutical and agrochemical inventions by means of supplementary protection certificates (SPCs) is extremely important to the pharmaceutical and agrochemical industries. Those industries are strongly affected by the need to go through rigorous and time-consuming regulatory approval of products before they can be placed on the market. This of course eats into the actual exclusivity period enjoyed by the originator company, during which R&D costs can be recovered. For this reason, it was considered appropriate to compensate companies in these areas, and the SPC is the tool to achieve that.

Current Legislation

The legal basis for granting SPCs in Europe is EU Regulation (EC) 469/2009 concerning the creation of an SPC for medicinal products and EU Regulation 1610/96 concerning the creation of an SPC for plant-protection products (“the SPC Regulations”). Both of these are directly applicable to all EU member states.

Effectively, the two SPC Regulations oblige and empower each member state to grant SPCs.

Unlike the EU regulations on trademarks and registered designs, the SPC regulation does not create a single EU-wide IP right. Therefore, at present, the SPCs which are granted on the basis of these regulations are national rights. This also means that, unlike registered designs and trademarks, the EU regulation is the only legislation which exists for member states; there is no parallel national IP right.

Brexit Impact on SPCs and SPC applications

In view of the impending Brexit, many companies active in life science R&D are currently asking themselves what impact the Brexit will have on their existing SPC portfolio and future SPC filing strategy if the UK actually leaves the EU.

Will the SPC Regulations continue to apply to the UK?

This is a key question, and the answer to this depends in part on how the Brexit is implemented.

If there is a so-called soft Brexit (whereby the UK leaves the EU but remains in the EEA), it is quite likely that the two SPC regulations will continue to apply to the UK, along with many other pieces of EU legislation. In this scenario, there would perhaps be little change.
The below sections consider the impact of this on existing SPCs and existing rights.

Impact on existing SPCs in the UK

If the Regulations no longer apply to the UK, this would remove the legal basis for the existence of the already granted SPC rights in the UK. Thus there is a theoretical possibility of a loss of rights. It is up to the UK legislators to do something about this, and they will surely put some transitional provisions in place which safeguard already granted IP rights. Once further information is known, we will issue a further newsletter on this.

Impact on UK SPC applications pending at the time of the Brexit

If the SPC regulations cease to apply to the UK, this will effectively leave the UK with no SPC legislation. The UKIPO will then not be able to grant any SPCs which were filed based on the regulation, or indeed do anything with those applications. It is an open question what will happen to these applications; presumably there will be some transitional provisions which allow the existing SPC applications to be “converted” to applications under the new corresponding national law, or maybe they will be automatically converted. Once further information is known, we will issue a further newsletter on this.

Impact on future UK SPC applications

Without SPC legislation, the UKIPO will also have no legal basis for receiving new SPC applications. It is reasonable to assume that the UK wishes to provide equivalent protection to the rest of Europe, in which case it will be necessary for the UK to put in place its own legislation providing a mechanism for extending UK patents and UK parts of European patents.

Since SPC law might not have the highest priority considering all the other implications that the Brexit might bring, it is rather likely that this new national law will resemble the already existing SPC regulations, at least at first. Once further information is known, we will issue a further newsletter on this.

Impact on Litigation

In the event of a hard Brexit, UK courts would no longer be bound by the rulings of the Court of Justice of the European Union (CJEU). Over the last years, the British courts have taken a very active role in the European SPC system and have very frequently challenged the position taken by the CJEU. The most important changes to the SPC practice in Europe, notably the Medeva judgement (C-322/10 of 24 November 2011) on the necessary protection of active ingredients by the basic patent and the Neurim judgment (C-130/11 of 19 July 2012) on SPCs for new therapeutic applications of known active ingredients, have been triggered each by a reference for a preliminary ruling from the UK Court of Appeal.

Some stakeholders believe that there is a possibility of a significant divergence developing between the SPC practice in the EU and the UK after the Brexit, even if the UK adopts new SPC legislation which closely resembles that of the EU regulations.

Even in the event of a soft Brexit and a scenario where the two Regulations still apply to the UK, some changes would happen. For example, SPC referrals from a UK court would no longer go to the CJEU, but to the EFTA courts. This may give the UK courts more discretion to deviate from CJEU case law, although it would remain to be seen whether the UK would wish to do so or not.
Impact on the Calculation of SPC terms

The term of an SPC is calculated by subtracting five years from the time period which has passed between the filing date of the basic patent and the first marketing authorisation in the EEA.

Depending on whether the UK becomes an EEA member following the Brexit, national UK marketing authorisations may no longer be relevant for the calculation of the term of the SPC sought for.

This may in turn lead SPC applicants to review their current regulatory strategies for obtaining marketing approval in Europe.

What should applicants do between now and the Brexit?

Since there is currently no alternative available to SPCs obtained by reference to the two SPC regulations, we see no reason why SPC applicants should already now change their SPC filing strategies.

For any pending applications, one might consider trying to expedite proceedings in the UK to make sure SPCs are granted before the UK leaves the EU. Although the Brexit can have consequences for both granted SPCs and pending applications, it seems to us that the uncertainty will be less for the granted rights because the transitional provisions might be simpler to put in place.

Once the Brexit date approaches, it may become relevant to consider whether it is better to apply pre-Brexit or post-Brexit; however, at present that discussion is premature. The differences may not be significant, and the number of applications where there will be a choice is likely to be small given the deadlines for filing SPC applications (i.e. within six months of (i) grant of the corresponding patent or (ii) approval, whichever of the two is later).

Long-Term Planning

After the Brexit and a hopefully smooth transition phase, special attention needs to be paid to the further development of the SPC practice in the UK. At HOFFMANN EITLE, we have a specialist team of patent attorneys based in Munich and London with extensive knowledge in SPC matters. We frequently advise on SPC proceedings before the patent offices, the national courts and the CJEU, and will be in a position to advise you in view of the upcoming changes.

Contact our Experts

Should you have any further questions or require specific assistance in this regard, please feel free to contact your usual HOFFMANN EITLE advisor or one of the below experts:

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