EIP

SPCs

It takes a significant financial investment to get a drug from lab bench to market, and many candidates fail in clinical trials. The usual 20 year patent term is generally not long enough to recoup the costs and compensate for the risks involved.

As a result, patent term extension regimes exist in many jurisdictions for pharmaceuticals. These aim to restore effective patent term which is lost due to slow regulatory approval processes, and in turn, incentivise research and development of new pharmaceuticals.

Patent term extensions offer valuable additional protection for patent holders in the field of pharmaceuticals – extensions of term can be worth millions daily for a blockbuster drug. Optimising available patent term extensions in key markets is an important consideration from the outset when preparing an IP strategy – it feeds into claim drafting, timing of filing and subsequent international prosecution strategy.

Patent term extension in Europe - what is an SPC?

A patent can last up to 20 years from the filing date and gives the proprietor the right to prevent third parties from carrying out certain infringing acts. However, medicinal and veterinary products require a marketing authorisation (MA) before they can be marketed and sold. This means that the patent proprietor is also prevented from selling the patented products until a MA has been obtained, reducing the period during which they can benefit from being the exclusive seller – this period is often referred to as the "effective patent term". Supplementary Protection Certificates (SPCs) extend the term of protection for active ingredients in medicinal, veterinary and plant protection products beyond the usual 20 year duration of a patent.

SPCs are national rights available in all EU states as well as at least the UK, Switzerland, Iceland and Norway. They take effect when the underlying patent expires (at 20 years

from filing). The SPC term expires at the sooner of (i) 15 years from the first Marketing Authorisation in the jurisdiction, or (ii) 25 years from patent filing date. Effectively, where there is a delay of more than 5 years between the patent filing date and grant of the marketing authorisation, an SPC can be used to extend the term of protection by up to 5 years. The length of the SPC is capped at 5 years to try to balance the interests of the patent owner and the public; to fairly compensate the patent owner for regulatory delay without overly restricting the entry of generics into the market upon expiry of protection.

Requirements

EU SPCs are granted under European Legislation and Regulation (EC) No 469/2009 applies to medicinal products for human and veterinary use. SPCs are also available for plant protection products, but this is outside the scope of this article. Article 3 of this EU regulation sets out conditions for obtaining a certificate:

Article 3 – Conditions for obtaining a certificate

A certificate shall be granted if, in the Member State in which the application… is submitted and at the date of that application:

a. the product is protected by a basic patent in force;
b. a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate:
c. the product has not already been the subject of a certificate:
d. the authorisation referred to in point (b) is the first authorization to place the product on the market as a medicinal product.

Whilst ostensibly clear, this law has required a lot of interpretation in practice and there have been many referrals to the Court of Justice of the European Union (the highest court in the EU which is ultimately responsible for construing EU laws). There is a complex web of case law which dictates what can be protected. The most important takeaways can be summarised as follows:

Interpretation of the Regulations

What constitutes a "product"?

The product must be an active ingredient or a combination of active ingredients. An active ingredient must have a therapeutic effect when administered alone. A combination of active ingredients refers to a combination which includes two or more active ingredients.

Different forms of an active that are "pharmaceutically equivalent" are the same product

for the purpose of SPC protection. This means that the scope of an SPC extends to pharmaceutically equivalent forms, even if such forms are not recited in the claims of the basic patent. Where pharmaceutical compounds are concerned, salts and esters are generally considered to be equivalent, unless there is some evidence to show that they differ in their therapeutic effect compared to the previous form of the active. For example, if there is a significant difference in safety and/or efficacy.

The same is true for a combination of an active with other therapeutically inert components, such as excipients, which are often used to formulate the dosage form of the active. As well as excipients, adjuvants are also commonly included alongside an active in a pharmaceutical dosage form. Adjuvants differ slightly from excipients in that they can enhance the therapeutic effect of the active when administered in combination. However, an active ingredient for the purpose of the SPC protection must have a therapeutic effect when administered alone. In this regard, adjuvants are not considered active ingredients and therefore cannot be the subject of an SPC. In practice, SPCs that cover an active will provide protection for a combination comprising the active in combination with an excipient or an adjuvant.

The situation regarding pharmaceutical equivalence for biological actives (e.g. peptides) is more complicated and there is less case law on the interpretation of the SPC regulations regarding these products compared to traditional small molecule drugs. Biological products are becoming more common and so the situation is likely to develop over time as we will no doubt see more and more applications for products, such as biosimilars, that fall under this grey area of the regulations.

What is a "basic patent" and when is the product considered to be "protected by a basic patent"?

A basic patent can be any patent that includes claims directed towards an active ingredient or combination of active ingredients for which there is a valid authorisation in place. The claims must define the product fairly precisely - a broad Markush formula which encompasses the product is likely not to be sufficient. The safest practice is to include a claim which is directed only to the precise product (or combination). This requires a good idea as to what the candidate compound will be when drafting the application, which in turn may push applicants to file applications later.

Whilst the product itself needs to be specifically defined, SPC protection is not only available for claims to the product as such. An SPC can also be granted based on a patent for a process of making the product or a use involving the product. The SPC is still limited by the scope of the patent claims, so would not cover the product as such in this situation. The purpose of the SPC is to extend the term of the protection – it cannot

extend the scope of protection conferred.

There may be more than one patent that meets these criteria for a given product and it is up to the patent owner to decide which to use for their SPC application. Product patents are most valuable as they offer the broadest protection, but other factors should also be taken into account including available SPC term (based on patent filing date in the case of EU SPCs) and the strength of the patent's claims. Best practice when drafting is to include a dependent claim to the specific product (the active ingredient or the combination of active ingredients), but this may not always be possible if the lead candidate is not known at that early stage.

What is an authorisation in accordance with Directive 2001/83/EC or Directive 2001/82/EC?

The two directives recited in the SPC regulation relate to medicinal products for human and veterinary use. Only products that fall under these directives can be the subject of an SPC. For example, SPCs cannot be obtained for medical devices, which are subject to regulatory approval but under a different EU directive. It should be noted that the applicant for a SPC must own the basic patent, but they do not need to own the authorisation.

When is the product considered to have already been subject to a certificate?

As discussed earlier, "pharmaceutically equivalent" forms are considered to be the same product for the purpose of SPC protection. When a SPC for an active has previously been granted, it is not possible to obtain a new SPC for an equivalent form, even though such a new product may well be subject to a new (later) marketing authorisation. This includes new salts or prodrugs, and new combinations of the active with excipients or adjuvants.

When is an authorisation considered to be the first to place the product on the market?

In some instances, an active is placed on the market for the first time as part of a combination product, and a later authorisation is granted relating to monotherapy. In such a case, the authorisation for the combination is the first authorisation for the purpose of an SPC relating to the combination or the active alone. In addition, the use for which the product has been authorised is also irrelevant. For example, where an earlier veterinary authorisation exists, an SPC cannot be granted based on a later authorisation for human use, even if the SPC is being sought for human use only.

Further Considerations

What is the scope of protection of the SPC?

"Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend… to… any use of the product as a medicinal product that has been authorised before the expiry of the certificate."

As discussed above, the SPC only covers the product which is subject to the authorisation. The SPC scope does not extend to other products encompassed in the patent claims but which are not subject to the MA. The SPC scope is also limited to the scope of the granted claims of the patent and only those claims which protect the product to the required degree of specificity.

However, for SPCs that cover a product as such, the protection covers any authorised medicinal use and so is extended by any subsequent MAs relating to the same active and granted during the SPC term. The subsequent MAs may relate to use of the product to treat a new therapeutic indication for example, and can be obtained by any party; they do not need to be obtained by the SPC owner. Product patents are therefore most valuable as basic patents. In contrast, SPCs based on use patents are limited to the claimed use(s) only.

Can the SPC term be extended?

The term of an SPC can be extended by an additional 6 months for medicinal products that have been tested for paediatric use (referred to as a paediatric extension). This extension is intended to incentivise paediatric research.

The SPC owner must submit a "paediatric investigation plan" (PIP) to the EMA. The PIP is assessed and, if approved by the EMA, the PIP study can then be completed. Once completed, the SPC owner can seek the additional 6 month term, regardless of whether the PIP results show that the product is suitable for paediatric use.

There are a number of procedural hurdles which must be met for the 6 month term to be granted, and limitations on whether it can be granted in some circumstances, the details of which are beyond this summary article. Please get in touch with your usual EIP contact to discuss this further if of interest.

When should the SPC application be filed?

The application should be filed within six months of the marketing authorisation being granted, or within six months of the patent being granted, whichever occurs later.

Brexit

Post-Brexit, SPCs in the UK are now governed by national UK law, albeit based on the corresponding EU legislation. This has implications in terms of the requirements for obtaining UK SPCs and their geographical scope.

Marketing Authorisation and Geographical Scope

Previously, under the EU system, it was possible to obtain an SPC covering the whole of the UK based on a marketing authorisation granted by the European Medicines Agency (EMA). Due to the Northern Ireland protocol, marketing authorisations in Northern Ireland are still handled by the EMA, whereas authorisations in Great Britain (GB) can now only be granted by the Medicines and Healthcare Products Regulatory Agency (MHRA). As a result, a UK SPC will only cover the whole of the UK if the product is subject to authorisations from both the EMA and the MHRA.

A patent owner can file their UK SPC application based on a single granted authorisation. Given that the separation of the EU and UK authorisation processes means that they are likely to be granted at different times, this requires a proactive approach, as it may not be possible to wait until both authorisations are obtained before applying for a UK SPC. If the patent is granted before either marketing authorisation (which is often the case), the deadline for filing an SPC is 6 months after the first authorisation to be granted by either the MHRA or the EMA.

The scope of protection can be extended to the whole of the UK later upon grant of the missing authorisation, so long as it is granted before the SPC takes effect (i.e. before the normal expiry of the basic patent). Both authorisations must be the first authorisations for the product in the respective territory.

Paediatric Extension

As with EU SPCs, a further 6 months SPC term can be obtained through a paediatric extension. A similar geographical restriction also applies to the availability of a paediatric extension as for the base UK SPC. A paediatric extension can only be obtained in a territory for which the SPC was initially granted. Additionally, if the initial SPC covers the whole of the UK, the requirements for the paediatric testing defined in the both the MHRA and EMA authorisations must be met for an extension to be obtained across the whole of the UK.

For example, if an EMA authorisation was not obtained, or was obtained after the SPC came into effect, the UK SPC would not cover Northern Ireland. A paediatric extension

would therefore not available in Northern Ireland. If a SPC covered the whole of the UK, a paediatric extension would only apply to the whole of the UK if the requirements for obtaining the extension were met in relation to both the EMA and MHRA authorisation. Otherwise, the geographical scope of the extension would be limited to Northern Ireland or GB only, even though the initial SPC term applied to the whole of the UK.

Windsor Framework

The Northern Ireland protocol has placed additional pressure on the UK pharmaceutical industry. Not only has it resulted in a change in the UK SPC procedure, but it has complicated medicine supply within the UK due to the significant volume of medicines that move between NI and GB. The Windsor Framework is a new agreement which simplifies trade within post-Brexit UK. The arrangements relating to medicines will take effect from 1 January 2025, at which point the EMA will no longer be responsible for medicines regulations in NI and the MHRA will issue UK-wide authorisations. This should simplify the UK SPC process, as the EMA authorisation will no longer be needed, and applications will be based on a single authorisation. However, is not yet completely clear if and how these new regulations will apply to SPCs applications filed in 2024 for which the application process would still be ongoing after 1 January 2025. Also of note is that the Windsor Framework only applies to products for human use, and does not apply to veterinary and plant protection products (for which UK SPCs are also available).

Manufacturing Waiver

The EU manufacturing waiver allows third parties to manufacture medicinal products that are subject to an SPC, if the manufacture is solely for the purpose of:

- export outside of the EU – this applies throughout the term of the SPC; or
- to stockpile for sale in the EU after SPC expiry – this only applies in the last 6 months of the SPC term.

The waiver was introduced to benefit generics manufacturers and to allow them to prepare for so-called "day 1 entry" into the EU market. Without the ability to manufacture the product prior to SPC expiry, they would not be ready to sell the product in the EU upon expiry of the SPC.

A similar waiver based on the EU legislation is still in operation in the UK. The UK's exit from the EU does however lead to a discrepancy in the rules regarding export in the EU and UK waivers. The UK is now considered "outside of the EU" for the purpose of export under the EU waiver. However, under the UK waiver, a UK-based generics manufacturer has to manufacture for export outside of the EU and the UK to satisfy the terms of the

waiver. This puts EU-based generics manufacturers in an advantageous position compared with UK-based manufacturers, as the terms of the EU waiver can be satisfied by exporting to the UK, but a UK manufacturer does not have the same benefit with respect to export to the EU.

Changes to the SPC regime

The current process for obtaining EU SPCs is quite burdensome. Even though the marketing authorisation is typically centralised (via the EMA), applications for SPCs must be filed at each of the national patent offices where extension of protection is sought.

As of 2023, it is possible to request a "Unitary Patent" which covers 18 EU countries. The system aims to reduce costs for patent owners and simplify potential litigation. In parallel with the new Unitary Patent, a Unitary SPC is being proposed by the European Commission. Some of the key takeaways from the proposal are:

- Unitary SPC would extend protection from a Unitary patent, and would cover the same countries;
- Unitary SPC applications would be processed via a centralised route, with examination handled by the EU IPO;
- the European Commission is also proposing that SPCs based on classical (i.e. non-Unitary) EP patents that use an EU-wide authorisation would need to be submitted via the centralised route;
- national SPCs based on national authorisations would still be handled by the national patent office in the relevant member state.

Patent Term Extension Outside of Europe

Many other commercially important markets of Europe including the US, Japan and China offer similar means to extend patent term for pharmaceuticals. However, whilst there are similarities, each jurisdiction has their own procedures and requirements. For example, the term of extension may be calculated based on different dates, and some may allow protection of products that cannot be subject to UK or EU SPCs. For some countries, fast patent grant is key and so patent prosecution should be accelerated. Strategic planning and patent portfolio management is required in order achieve the best possible patent term in key jurisdictions of interest.