European Supplementary Protection Certificates (SPCs) for Pharmaceuticals

A practical guide

Patent protection remains a crucial form of market exclusivity for new pharmaceutical drugs. But with research time and regulatory requirements delaying entry to market, other forms of exclusivity are needed to augment protection, and secure product revenue streams, before generic products enter the market and disrupt prices.

Companies carrying out pharmaceutical research will be aware of patent protection, but perhaps less so of other forms of intellectual property rights (IPRs) that compliment patents.

Supplementary Protection Certificates (SPCs) are linked to a granted patent, and are available across Europe. Once granted, SPCs provide additional protection for a marketable pharmaceutical or agricultural product once the related patent has expired. Whilst SPCs require patent protection to have existed, they are a separate right, and are an invaluable way of extending market exclusivity for a marketable medicinal product.

Companies looking to take a pharmaceutical product to market in Europe, either themselves or in collaboration with a partner, should consider SPCs as part of their IP strategy.

The reason for SPCs

Medicines and agricultural products take many years to reach the market due to the requirement to obtain regulatory approval. This often leaves only a few years of patent protection once the product is marketable before a generic version may be sold, driving down market prices. Considering that average R&D spend for marketable medicine is around 3 to 11 billion dollars, it is often challenging to recoup those costs before markets are disrupted by competitors.

For this reason, most significant pharmaceutical markets around the world offer medicines special patent term extensions to compensate for this delay. In Europe, this extension is referred to as a Supplementary Protection Certificate, or SPC.

An SPC is an intellectual property right that extends the term of protection for a marketable medicine covered by a patent beyond the normal 20 years. It is not an extension of the patent itself, but instead an independent right that comes into force the day after the expiry of the patent. SPCs were borne out of EU legislation, and are available in all EU territories, but similar rights have been established in non-EU countries, such as Iceland, Liechtenstein, Norway, and Switzerland. Prior to its departure from the EU, the UK benefited from the SPC system, and it still does now, however, some BREXIT-related issues are explored later.

SPCs are only available for human or veterinary medicines (pharmaceuticals and biologics) and for plant protection products (things like insecticides and herbicides). SPCs are not available for any other form of regulated product, such as medical devices, despite numerous attempts over the years to try.

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What is the Scope of an SPC?

An important difference between a patent and an SPC is that the market protection offered by an SPC is usually significantly narrower than a patent. A patent will typically cover a range of structurally related compounds or components. An SPC on the other hand only protects the product for which marketing approval has been granted – usually a single active ingredient.

To obtain an SPC, the marketable product must be "protected by a patent". Whilst this seems straightforward enough, the legislation does not make clear what this actually means and so a large body of case law has built up around this question which is still yet to be settled. 2020 saw the Court of Justice of the European Union (CJEU) provide decisive guidance on this matter. [1]

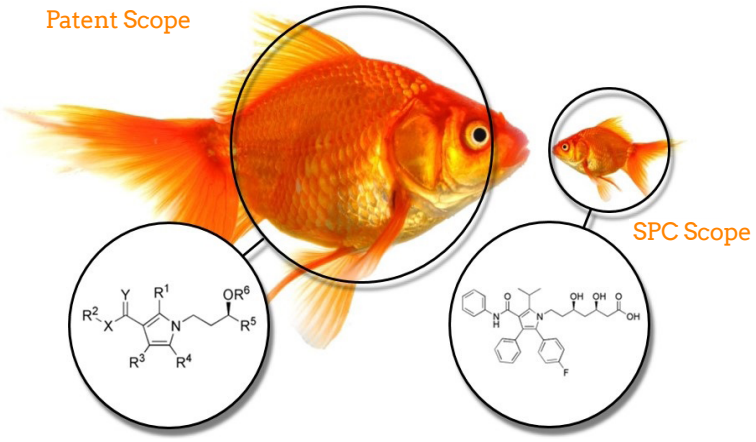
It is not enough for the medicinal drug to be covered by the patent. If not mentioned in the claims, the product must be directly and unambiguously derivable from the description, although individualisation of the medicine is not necessarily required. In particular, the test for whether a product is disclosed in a patent appears to be less stringent than the test for added matter at the European Patent Office (EPO). [2]

The CJEU stopped short of saying that the product must be explicitly mentioned in the patent. In fact, it appears to be acceptable for the patent to define the product in terms of its function, particularly for biologics. This notwithstanding, it remains highly recommend to base an SPC application on a patent in which the medicine is specifically described.

And what do we mean by a medicinal "product"? One might think of a product as being the marketable drug. A new formulation of a known medication marketed under a different name, particular if used to treat a different disease, certainly sounds like a new product. However, this is not the legal interpretation of "product" in relation to SPCs.

SPC law refers to a product as solely the active ingredient. [3]

It is also clear from recent CJEU guidance in the Santen [4] decision that SPCs are intended to reward the extra work needed to discover new drugs. This overruled the previous gold standard set in Neurim, [5] and has confirmed that SPCs are not available for new uses of a medicinal product marketable in Europe. [6]



What is the Duration of an SPC?

SPCs are to compensate the delay in obtaining a marketing authorisation. Their duration is derived from the difference in time between filing the related patent and the date on which the marketing authorisation is issued. But protection cannot simply be extend by the difference between those two dates. A balance is required between the rights of the patentee and those of the public to avoid a patent owner's market exclusivity being excessive.

The EU decided that SPC protection cannot exceed five years, and the total amount of protection offered by a granted patent and an SPC is not more than 15 years. SPCs for products with paediatric indications benefit from an additional six month duration extending SPC protection to five-and-a-half years, with the total amount of protection offered by a patent and an SPC being no more than 15½ years.

[1] CJEU Case C-650/17 - Royalty Pharma Collection Trust
[2] https://www.gje.com/spcs-what-it-means-to-be-protected-by-a-patent/
[3] CJEU Case C-210/13 – GlaxoSmithKline Biologicals
[4] CJEU Case C-673/18 - Santen
[5] CJEU Case C-130/11 - Neurim Pharmaceuticals (1991)
[6] https://www.gje.com/santen-a-clear-view-of-drug-repurposing-and-a-loss-of-sleep-for-those-relying-on-neurim/

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What are the requirements for an SPC?

Two fundamental requirements for an SPC application are

1. a granted patent protecting the medicinal product in the country of interest; and
2. a granted marketing authorisation for the medicinal product in that country.

The patent may be a direct national filing, or granted via the EPO. The patent must protect the product and be in force, i.e. not expired or lapsed. The marketing authorisation may be issued by the relevant national regulatory body, or by a centralised procedure, such as that offered by the European Medicines Agency, the EMA.

Marketing authorisations issued by the EMA currently cover all EU countries, and Iceland, Norway and Liechtenstein. They do not cover Switzerland, neither do they cover Great Britain following BREXIT. Technically, they do not cover Northern Ireland, however the situation there is more complex, as examined below.

As SPCs are intended to compensate new active ingredients, it is crucial that the marketing authorisation is the first authorisation to place that product on the market in the particular country.
Importantly, an SPC must be applied for within six months of the latest of

i. the grant of the patent; or
ii. the grant of the marketing authorisation.

In view of this, it is extremely important that those dealing with a company's IP and its regulatory department keep each other informed of progress.

The applicant for the SPC must be the owner of the basic patent, not the company having the marketing authorisation. An exclusive licensee whom has been given full control of the patent must ask the patentee to apply for the SPC on its behalf. For this reason it is highly recommended that any transfer of rights in the patent has been recorded in each relevant country before an SPC application is filed.

As SPC applications are filed at national patent offices, representation in each country is required. We work with a network of attorneys across Europe specialising in SPCs to ensure that this is done correctly on your behalf.

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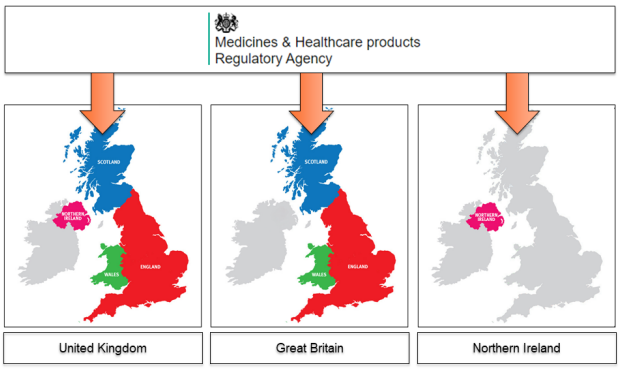
UK SPCs and BREXIT

EU law no longer applies in the UK. Patent law remained largely unchanged as the European Patent Office sits outside of the remit of the EU. However, leaving the EU has had an impact on SPCs, and it is important to appreciate these differences.

Marketing authorisations issued by the EMA no longer cover the UK. So on 1 January 2021, authorisations from the EMA were automatically converted into equivalent UK authorisations at the Medicines & Healthcare Products Regulatory Agency, the MHRA. In addition, under the UK's EU Withdrawal Act the UK incorporated all EU SPC law into UK national law. Subsequent adaptations were made to enable the law to function in its new UK context, in particular, changes were necessary in view of the EU's continuing impact on Northern Ireland, which is governed by the Northern Ireland Protocol. Those changes include the UK being able to issue marketing authorisations covering the whole of the UK, Great Britain (England, Scotland, and Wales), or just Northern Ireland.



This is because the Northern Ireland Protocol places Northern Ireland in the UK customs territory and under UK law that is not already devolved to Northern Ireland, whilst simultaneously aligning it with EU regulatory laws on medicines and pesticides.

Great Britain is no longer bound by those EU regulatory laws, and so there is potential for divergence in the UK between Northern Ireland and Great Britain in relation to regulation of medicines. To address this possible partitioning of regulations in the UK, the MHRA can now issue separate UK, Great Britain and Northern Ireland marketing authorisations.

The first marketing authorisation to issue, UK, GB, or NI, starts the six-month time period for filing an SPC application (assuming the related patent has already been granted). The remaining authorisations may be added to the SPC application within six-months of their grant, as long as the SPC has not yet entered into force. Inaddition, any authorisations granted in the European Economic Area (EEA) which predate the earliest of the UK, GB, or NI authorisations, may impact the duration of a UK SPC.

Paediatric extension requests post-BREXIT remain relatively unchanged. The request should be made no later than two years before the SPC is due to expire, and a copy of the paediatric investigation plan (PIP) outcome should be provided in combination with information on the territories that the authorisation covers. One positive consequence of BREXIT is that evidence of marketing authorisations in EU Member States is no longer needed.

Finally, paediatric extensions may only extend an existing SPC. So if a request is made while the SPC is in force, the paediatric extension will apply only in a territory where the SPC already provides protection. Similarly, if the paediatric extension only applies to part of the SPC territory, such as just GB, then the SPC will only be extended in that territory even if the SPC is also in force in NI.

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Lipitor case study: Potential impact of an SPC

From the start of 2010, the pharmaceutical industry was faced with a significant number of drug patent expirations, which became commonly referred to as a "patent cliff". In November 2011 alone, patent protection ended for four major drugs – Lipitor (atorvastatin), Caduet (amlodipine/ atorvastatin), Combivir (lami vudine/zidovudine), and Solodyn (minocycline extended release tablet).

Lipitor (atorvastatin) is a statin that was widely used to prevent cardiovascular disease. In 2011, statins had hit the headlines promising everyone over a certain age a reduced risk of heart disease. Pfizer pushed the boundaries of advertising budgets making Lipitor the go-to statin, and the best-selling pharmaceutical product ever. [8] Protected by a patent, and costing up to $168 per month, Lipitor reached peak sales of nearly $13 billion per year, accounting for up to 27% of Pfizer's revenue. The problem was that Lipitor's patent was about to expire, and when it did, Pfizer fell off one of the largest patent cliffs the pharmc sector has seen as sales of Lipcr plummeted.
Lipitor sales dropped to under $2 billion per year, representing a loss of about $11 billion in revenue. [9]

The expiry of the patent covering Lipitor was not the only event that affected revenue. Pfizer's aggressive marketing campaign was fast becoming less effective, and alternative, cheaper statins were already on the market.

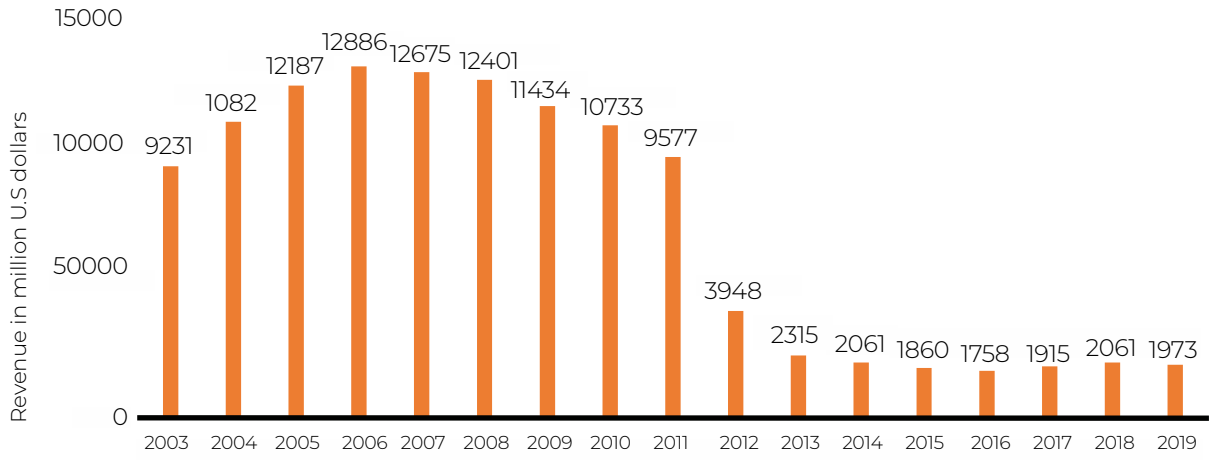
Lipitor sales data cover the whole world, and Europe was a relatively small market compared to the US, but this example highlights the important of leveraging every form of intellectual property protection possible for a medicinal product.

Summary

Companies looking to recoup the substantial cost of medicinal product R&D need to consider the availability of SPCs to prolong their market exclusivity, increasing product revenues.

If you would like to discuss any of the points raised, and how Supplementary Protection Certificates may affect your business, please contact Ian Jones (ian.jones@gje.com)

[7] https://www.uspharmacist.com/article/drug-patent-expirations-and-the-patent-cliff
[8] https://ihsmarkit.com/research-analysis/lipitor-patent-expiration-atorvastatin-sales.html
[9] https://www.statista.com/statistics/254341/pfizers-worldwide-viagra-revenues-since-2003/



Statistics courtesy of Statista https://www.statista.com/statistics/254341/pfizers-worldwide-viagra-revenues-since-2003/

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