

The must-know facts about patent term extensions in Europe

Patent term extensions are key tools for the protection of drugs in Europe. Understanding their complex legal framework is just as crucial

By **Ralph Minderop, Arwed Burrichter and Natalie Kirchhofer**, COHAUSZ & FLORACK

With over 15 referrals on the subject to the European Court of Justice (ECJ) in the past three years, the interpretation of the law governing patent term extensions has become increasingly complex. This article provides up-to-date answers to the most frequently asked questions on supplementary protection certificates (SPCs).

What is an SPC?

Similarly to the patent term extensions available in the United States under 35 USC §156, European patent law offers the possibility to apply for an SPC in order to compensate patent holders for the regulatory delays caused by marketing authorisation procedures for medicinal and plant protection products. By way of an SPC, the statutory 20-year maximum patent term can be extended by up to five years.

What is the significance of SPCs compared to regular patent filings?

The most recent statistics of the European Patent Office show that around 12,300 pharmaceutical and biotech patent applications were filed on average each year between 2009 and 2011. By contrast, between 2009 and 2012, only 58 SPC applications were filed on average each year with the national patent authorities of Germany and the United Kingdom – the EU countries with the highest patent filings.

This discrepancy results from the fact that SPCs can be obtained only for products that have been authorised for the first time as medicinal products in the European Union. With only about 20 to 40 new molecular entities being authorised for medicinal use each year (see www.vfa.de), the number of possible SPC applications is limited.

Despite the scarcity of SPCs, they have tremendous economic significance for pharmaceutical and biotech companies. Unlike most patents, each granted SPC protects a commercialised medicinal product. Because of the immense upfront R&D costs incurred to bring a drug to market, the usual 20-year patent term is often insufficient to allow for any return on investment. Against this background, SPCs are indispensable tools to amortise the costs that accrue before a marketing authorisation can be obtained. Thus, at the end of the patent term – when, in the case of best-selling drugs, billion-dollar revenues are at stake – each day of additional patent term extension gained through an SPC counts.

For which European countries can SPCs be obtained?

SPCs for medicinal products in the European Union are governed by EU Regulation 1768/92, which came into force on January 2 1993 and was codified and replaced by EU Regulation 469/2009 (referred to further below as the MP-SPC Regulation). A similar legislative framework is in place for SPCs for plant protection products, although this is not discussed further in this article. These regulations are binding and directly applicable in all 27 EU member states. Of the non-EU countries for which European patents can be granted, several – including Switzerland,

Macedonia and Albania – offer national provisions that are similar to the MP-SPC Regulation. Turkey is a notable exception in that no SPC-like patent term extension is available there. In this article, only SPCs within the European Union are discussed.

What is the duration of an SPC?

SPCs extend the patent term for a period that is equal to the time that elapsed between the filing date of the patent application and the date of the first marketing authorisation in the European Union, minus five years. The overall term of an SPC may not exceed five years. Consequently, an SPC may afford a maximum patent duration of 25 years, or – when calculated from the date of first marketing approval – an effective patent exclusivity period of 15 years after first marketing authorisation. Importantly, in calculating the duration of SPCs, the first marketing authorisation in the European Community (ie, the European Union plus the EEA states) is important, which can differ from the first marketing authorisation in the country in which the SPC application is being filed (Article 13 of the MP-SPC Regulation).

The term of an SPC can be further extended by six months if the marketing authorisation preparations included all of the studies required in compliance with an agreed paediatric investigation plan. This special possibility for SPC extension was introduced by the EU Paediatric Medicines Regulation (1901/2006), which came into force in late 2007. This regulation provides further incentives for the pharmaceutical industry to include clinical trials specifically addressing paediatric uses of a drug. The ECJ recently clarified in *Merck* (C-125/10) that an SPC can also be granted with a zero or negative term. The grant of such an SPC can be desirable, as the paediatric extension is possible only if an SPC is in place. Hence, for example, a six-month extension of a negative-term SPC, provided that the negative term is less than six months, can result in a positive patent term extension for the proprietor.

What is the deadline for filing an SPC application?

An SPC application must be filed with each competent national IP office within six months of receiving the marketing authorisation for

that country or within six months of obtaining the basic patent, whichever is the later (Article 7 of the MP-SPC Regulation). Calculation of the SPC filing deadline takes into account the first market approval in the country of filing, not the first market approval in the European Economic Area.

The marketing authorisation relevant for the six-month deadline can be issued either by the European Medicines Agency under the centralised procedure of EU Regulation 2309/93 or at national level by the competent national drug approval body.

The application for the six-month paediatric extension of an SPC under EU Regulation 1901/2006 can be filed together with the SPC application, as well as at a later stage – although no later than two years before the expiry of the SPC.

What subject matter is eligible for SPC protection?

Only an active pharmaceutical ingredient or combination of active pharmaceutical ingredients that is protected by a basic patent and has obtained an administrative marketing authorisation before being placed on the market as a medicinal product can be the subject of an SPC. The active pharmaceutical ingredient protected by the SPC will generally be interpreted so as also to include any closely related derivatives, such as salts or esters, as long as they are also protected by the basic patent (*Farmitalia/Idarubicin*, C-392/97). As defined in Article 1 of the MP-SPC Regulation, ‘basic patent’ means:

- a patent protecting the active pharmaceutical ingredient as such;
- a process to obtain the product; or
- an application of the product.

This also includes claims for use and method of treatment, as well as claims relating to the active principle of the product. Formulation patents and medical device patents cannot be the object of SPCs.

What are the conditions for obtaining an SPC?

Applications for SPCs must be filed with each national IP office on a country-by-country basis (Article 9 of the MP-SPC Regulation).

An SPC may be granted only to the holder of the basic patent or its successor in title (Article 6). In accordance with Article 3 of the MP-SPC Regulation, an SPC can be granted only if, at the filing date of the SPC application:

- the basic patent protecting the product is in force;
- a valid marketing authorisation has been granted in accordance with EU Directive 2001/83/EC (pharmaceutical products) or EU Directive 2001/82/EC (veterinary products);
- the product has not already been the subject of an SPC belonging to the same person; and
- the marketing authorisation is the first to have been granted for this product in the country for which the SPC application is filed.

What criteria should be used to determine whether a product is protected by a basic patent according to Article 3(a) of the MP-SPC regulation?

Opinion and practice were divided across Europe regarding the test to be used to determine properly whether a product for which a marketing authorisation has been issued is protected by a basic patent according to Article 3(a). Some jurisdictions (most notably Germany, the United Kingdom, the Netherlands and France) relied on the express wording of the basic patent (the disclosure test), whereas courts in other jurisdictions (eg, Belgium) resorted to the patent's scope of protection (the infringement test).

In November 2011 the ECJ provided some clarification on this issue in its decision in *Medeva BV* (C-322/10), *Georgetown University* (C-422/10), *Yeda* (C-518/10), *University of Queensland* (C-630/10) and *Daiichi* (C-6/11). The ECJ ruled in favour of the disclosure test, stipulating that an SPC can be granted for a combination product only if all active pharmaceutical ingredients in the combination are "specified [or identified] in the wording of the claims" of the basic patent. Hence, a patent claiming active pharmaceutical ingredient A cannot serve as a basic patent for a combination SPC directed to active pharmaceutical ingredients A+B if the combination of active pharmaceutical

ingredient A with active pharmaceutical ingredient B is not "specified/identified in the wording of the claims". Thus, even though the combination of active pharmaceutical ingredients would infringe the patent claiming the single active pharmaceutical ingredient, the combination is not protected by the basic patent in the sense of Article 3(a). What degree of "specification/identification in the wording of the claims" is necessary and sufficient is, however, unclear. This question has been referred to the ECJ for clarification (Cases C-493/12 and C-443/12).

When prosecuting patent applications for new active pharmaceutical ingredients, it seems advisable to direct a sub-claim to the product for which an SPC will most likely be applied for and to ensure that this product is expressly mentioned in the claim.

Is it possible to obtain a single-product SPC based on a marketing authorisation for a combination product comprising multiple active pharmaceutical ingredients?

This question has also been clarified by the ECJ in the November 2011 case quintet referred to above. The ECJ held that the SPC 'product' can be defined as a single active pharmaceutical ingredient (or as a sub-combination active pharmaceutical ingredient), even when the combination drug or vaccine for which the marketing authorisation was obtained includes further active pharmaceutical ingredients. Hence, an SPC for product A can be obtained based on a marketing authorisation for a combination product A+B.

What is the scope of protection afforded by an SPC?

According to Article 4 of the MP-SPC Regulation, the protection conferred by an SPC shall – within the limits of the protection conferred by the basic patent – extend only to the product covered by the marketing authorisation and for any use of the product as a medicinal product that has been authorised before the expiry of the SPC. In *obiter dicta* in the ECJ case quintet mentioned above and the subsequent decision in *Novartis v Actavis* concerning valsartan (C-442/11 and C-574/11), the ECJ clarified that an SPC provides the same protection as the basic

patent against an unauthorised use of the product in the form of any medicinal product that contains that product. Accordingly, sale of a combination product A+B would infringe an SPC to product A.

Is it possible to cover several products with an SPC or to obtain several SPCs per basic patent?

As a rule, an SPC can cover only a single product – that is, an active pharmaceutical ingredient or combination of ingredients. Combinations of two or more active pharmaceutical ingredients can be the subject of an SPC only if the basic patent identifies the specific combination in the wording of the claims (see above).

Until recently, it was established case law that if a patent protected different products, each could be subject to different SPCs. To the surprise of many, the ECJ appears to have concluded in the case quintet of November 2011 that there might be only one SPC per basic patent. However, it is questionable whether the ECJ really intended to change case law in this way. Possibly, what the ECJ meant was that there can be only one SPC per product per basic patent. National courts in the United Kingdom and the Netherlands have referred this issue to the ECJ for clarification (Cases C-443/12 and C-484/12). Until the ECJ issues its decision, it may be advisable to separate the subject matter of an originally filed patent application into several divisional applications in order to ensure that separate patents are granted for the different products.

Despite the uncertainties regarding the number of SPCs that can be obtained per patent, it is established case law that it is impossible to obtain more than one SPC for the same product and indication. A notable exception to this rule is when the underlying patents are owned by different parties, which is known as a third-party SPC (see *AHP Manufacturing BV v Bureau voor de Industriële Eigendom*, C-482/07, and *Biogen Inc v Smithkline Beecham*, C181/95).

What must be considered when filing SPCs for combination products?

In Article 1 of the MP-SPC Regulation, the ‘product’ that can be the subject of an SPC

is defined as “the active [pharmaceutical] ingredient or combination of active ingredients of a medicinal product”. Hence, in terms of SPC law, a product comprising a single active pharmaceutical ingredient and a product comprising the same ingredient in combination with another are two different products, with each potentially eligible for separate SPCs. For an SPC covering a combination product to be granted, it is generally necessary that the summary of product characteristics accompanying the marketing authorisation specify the combination of active pharmaceutical ingredients in the qualitative and quantitative composition section. It is generally insufficient for the summary of product characteristics to stipulate that the product is authorised (only) for use in combination therapy with another drug. Hence, strictly speaking, only fixed-dose combination products (ie, a formulation of two or more active ingredients combined in a single dose form) can be covered by a combination SPC.

How can SPCs be forfeited or lost?

SPCs are linked to the validity of the basic patent for which they were issued. Therefore, an SPC becomes invalid if the underlying basic patent has lapsed or is revoked, or is limited to an extent that it no longer protects the product for which the SPC was granted (Article 15 of the MP-SPC Regulation). Moreover, an SPC lapses if:

- the certificate holder surrenders it;
- the certificate holder fails to pay the annual fees in time; or
- the marketing authorisation for the respective medicinal product is withdrawn (Article 14).

Furthermore, SPCs can be invalidated by third parties in national nullity proceedings before the competent national courts.

What needs to be observed during prosecution of SPC applications?

As noted above, even in Germany and the United Kingdom, under 60 SPC applications are filed each year. In EU countries with less economic weight, the number of SPC filings is even smaller. The tremendous economic

importance of SPCs means that it is advisable to appoint a lead counsel in Europe to manage, coordinate and oversee the diverse national SPC examination proceedings. Furthermore, the prosecution strategy and claim language of the basic active pharmaceutical ingredient patent should be adapted well before the patent is granted, to allow for effective and comprehensive filing of an SPC. For cost and strategic reasons, it is expedient to adopt a single wording for the SPC product description in the applications and one consistent response strategy to possible objections raised in the different national examination proceedings. **iam**

COHAUSZ & FLORACK

Patent und Rechtsanwälte, Bleichstrasse 14

D-40211 Dusseldorf, Germany

Tel +49 211 90 490 0

Fax +49 211 90 490 49

Web www.cohausz-florack.de



Ralph Minderop

Senior partner

+49 211 90 490 0

rminderop@cohausz-florack.de

Ralph Minderop is a senior partner with COHAUSZ & FLORACK and a European and German patent attorney. Dr Minderop provides strategic IP advice and has extensive experience in the prosecution and litigation of patents in the fields of life sciences, pharmaceutical chemistry and general chemistry on behalf of German and international clients. He holds a PhD in biochemistry.



Arwed Burrichter

Senior partner

+49 211 90 490 0

aburrichter@cohausz-florack.de

Arwed Burrichter is a senior partner with COHAUSZ & FLORACK, and a renowned and highly experienced European and German patent attorney. Dr Burrichter prosecutes and litigates patents in the fields of pharmaceuticals, general chemistry, polymer chemistry and biochemistry; he also advises on strategic IP decisions. Dr Burrichter obtained his PhD in chemistry from the University of Southern California, Los Angeles.



Natalie Kirchhofer

Technical expert

+49 211 90 490 0

nkirchhofer@cohausz-florack.de

Natalie Kirchhofer is a graduate in biochemistry from the University of Tübingen. She attended Rockefeller University, New York as a Fulbright scholar and subsequently obtained a PhD from the Max-Planck Institute of Biochemistry in Munich, investigating DNA double-strand break repair mechanisms. Dr Kirchhofer joined COHAUSZ & FLORACK in October 2010 and is currently training as a patent attorney.