MEISSNER BOLTE

Supplementary Protection Certificates

Unique Protection for Medicinal Products and Plant Protection Products

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The Supplementary Protection Certificate

A patent grants its owner an exclusive right to use the invention for twenty years. This period represents a compromise between a reward for publishing the invention and a restriction of free competition. In the case of inventions relating to medicinal products or plant protection products, usually only a part of this twenty-year period can be utilized by the patent owner: the approval procedure required for placing the medicinal product or plant protection product on the market falls within this twenty-year protection period.

In order to support research into new medicinal products and plant protection products, a "compensation scheme" has been set up within the European Union. Protection for a medicinal product or plant protection product can be extended beyond the twenty-year period conferred by a patent by up to five further years, this is by means of a Supplementary Protection Certificate ("SPC"). If a marketing approval application for a medicinal product includes the results of studies conducted in compliance with an agreed paediatric investigation plan, and if the medicinal product is authorized in all EU countries, a further six months may be granted.

An SPC application is based on an applicant's patent and a valid authorization to place the product on the market. Within the limits of the protection conferred by the patent, the SPC confers protection to the product covered by the MA.

An SPC grants its owner similar rights as conferred by the patent. In particular: the SPC prohibits competitors to place a product, which is subject-matter of the SPC, onto the market in the respective member state of the European Union without the consent of the owner of the SPC.

Exceptions for the effect of SPCs concern the production of protected medicinal products for export to countries outside the European Union, or production and stockpiling of protected medicinal products within the European Union for day-1 entry into the European market after expiration of the SPC ("SPC manufacturing waiver").

The SPC is an extremely valuable tool for extending the term of protection for economically important products at comparably low costs and should receive the highest attention by any pharmaceutical or agrochemical company.

7 “Must-Knows”

1

Extension of the Exclusive Right of Use for Medicinal Products and Plant Protection Products

Protection for a medicinal product or plant protection product can be extended beyond the twenty-year period conferred by a patent by up to a further five and a half years (five years for plant protection products) by means of a Supplementary Protection Certificate (“SPC”); this can be achieved for comparably little extra investment.

2

Little Extra Investment

The two main requirements for SPC application are a valid patent and a valid authorization to place the product on the market (“MA”). Given that successful companies typically obtain patent protection for promising inventions and they, or their licensees, apply for an MA for the most promising medicinal or plant protection products, both prerequisites for the SPC application are already at hand! Moreover, the SPC applicant must be the owner of the patent, but it is not required that the SPC applicant is also the owner of the MA! From the patentee’s perspective, the only additional investment is, therefore, the cost of the prosecution of the SPC application and the additional renewal fees. This is particularly important for medicinal products or plant protection products, the development of which may often not begin to generate revenue until the end of the term of the corresponding patent.

3

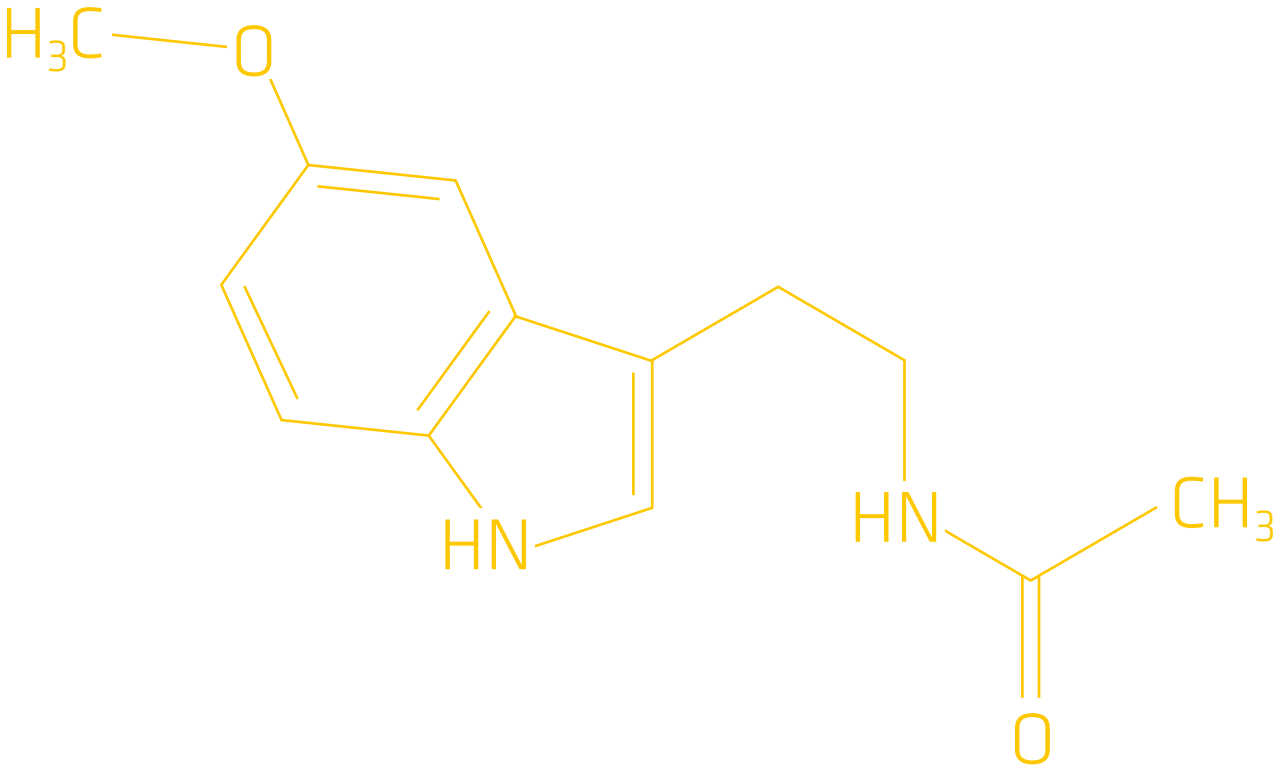
Term of Protection of the SPC

The SPC can be effective for up to five years after the expiry of the patent. The exact period is calculated from the time between the filing of the patent application on which the SPC application is based and the date of the first MA for the product in the European Economic Area (EEA), minus five years. If the MA application is for a medicinal product and includes a paediatric investigation plan, and if the medicinal product is authorized in all EU member states, the duration of the SPC may be extended by a further six months. Thus, a term of five and a half years of protection can be obtained!

4

Broader Protection Compared to Protection Conferred by Data Exclusivity and Market Exclusivity

For a period of eight years from the first MA of a medicinal product in the European Union, an application for an MA for a generic medicinal product is inadmissible without the consent of the applicant of the approved medicinal product (so-called “data exclusivity”). For a further two years, such a generic medicinal product may not be placed on the market (so-called market exclusivity). The market exclusivity can be extended for a further year if the approval of a new therapeutic indication with significant clinical benefit is granted within the eight-year period. Often, protection conferred by an SPC ends at a later point of time than the protection conferred by data exclusivity and market exclusivity. Moreover, an SPC can be used to exclude any medicinal product falling within the scope of the SPC from the market, not only generic medicinal products!



5 National Route to SPCs

Applications for SPCs are filed at the national patent offices of the member states of the European Union. Each patent office examines whether the requirements for grant of an SPC are fulfilled in the respective member state, possibly then granting an SPC with effect for that member state. Even if the requirements for grant of an SPC are not fulfilled in one member state, the requirements for obtaining an SPC may be fulfilled in other member states!

6 Timing is Essential

Applications for SPC protection must be filed within a period of six months from the grant of the MA or from the grant of the patent (whichever is later). Since several patents or patent applications and other parties' MA and SPC applications may be of relevance for the SPC application, we recommend planning the strategy for SPC application as early as possible. In particular, it is advisable to coordinate the department responsible for the MA with the lawyers and patent attorneys at an early stage.

7 SPC Manufacturing Waiver

In 2019, the "SPC manufacturing waiver" was introduced across the European Union. Under strict conditions, SPC protection no longer extends to the manufacture and storage of a medicinal product which is the subject matter of an SPC. The waiver applies to the production and export of the medicinal product to countries outside the EU, as well as to production and stockpiling of the medicinal product within the European Union for day-1 entry into the European market after SPC expiration. The waiver allowing production and stockpiling for day-1 entry, however, will not be earlier than six months before the expiry of the SPC. The SPC waiver does not extend to bringing the medicinal product on the market within the European Union during the term of the SPC, to this end the SPC's effect within the European Union is essentially not reduced!

Fundamentals

In order to support research into new medicinal products and plant protection products, the European Commission and the European Parliament adopted regulations, namely Regulation (EEC) No 1768/92 of 18 June 1992 concerning the SPC for medicinal products (later amended by Regulation (EC) 469/2009 and Regulation (EU) 2019/933) and Regulation (EC) No 1610/96 of 23 July 1996 concerning the SPC for plant protection products.

Such regulations have immediate and binding effect in all member states of the European Union. One intention of the European Commission was to avoid a heterogeneous development of SPC legislation within the European Community. The USA and Japan introduced in 1984 and 1988, respectively, compensation for the shortened term of protection for pharmaceutical products due to regulatory review by authorities. As a result of this, individual European states considered the introduction of similar compensation, effectively forcing the European Commission to take action in order to avoid different legislations within member states of the European Union.

According to Article 3 of the regulations, a SPC 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 patent in force;**

b **a valid authorization to place the product on the market as a medicinal product, respectively plant protection product, has been granted (in accordance with Directive 2001/83/EC or Directive 2001/82/EC or in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national law);**

c **the product has not already been the subject of an SPC;**

d **the authorization referred to in point (b) is the first authorization to place the product on the market as a medicinal product or plant protection product.**

Requirements (c) and (d) are rather formal requirements: according to current case law, (c) must be understood to mean that the same applicant may not be granted two SPCs for the same product. Thus, the two main assets for SPC application are (a) a patent and (b) a MA. Since the majority, if not all, successful companies patent all promising inventions and they or their licensees apply for an MA for the most promising medicinal or plant protection products, both assets required for SPC application may already be in place. Moreover, the SPC applicant must be the owner of the patent, but it is not required that the SPC applicant is the owner of the MA! From the patentee's perspective, the only additional investment is therefore the cost of the prosecution of the SPC application and the additional renewal fees.

It is important to note that, according to Article 1 of these regulations, the term "product" means the active ingredient/substance or combination of active ingredients/substances of a medicinal/plant protection product. In other words, a SPC shall only be granted if an active ingredient/substance or a combination of active ingredients/substances fulfils the above requirements (a) to (d). The literal interpretation of these regulations actually leaves de facto no room for the grant of SPCs based on new applications or new formulations of an active ingredient/substance with prior MA or of a combination of active ingredients/substances with prior MA.

Nevertheless, in a judgement (C-130/11 - Neurim) by the Court of Justice of the European Union (CJEU) in 2012, the CJEU departed from the literal interpretation of the SPC regulation for medicinal products. In this judgment, the CJEU did not find a previous veterinary MA of one active ingredient preclusive for the grant of an SPC for a different therapeutic application of the same active ingredient in humans. While this judgment and its significance for other cases remained disputed, SPCs for medicinal products with new therapeutic applications were subsequently generally granted in European countries.

In a judgment of the CJEU dated 9 July 2020 (C-673/18 - Santen), the CJEU returned to the literal and thus more restrictive interpretation of the SPC regulation for medicinal products. The CJEU took the position that an MA cannot be considered to be the first MA, for the purpose of the regulation, where it covers a new therapeutic application of an active ingredient or of a combination of active ingredients, if that active ingredient or combination has already been the subject of an MA for a different therapeutic application.

The SPC legislation and jurisdiction, which has led to numerous referrals to the CJEU, has been continuously evolving over the past thirty years and further developments are to be expected! Because of the high impact of SPCs on the pharmaceutical and agrichemical industry, it is necessary to remain updated on any and all new developments in this field.

It remains to be seen how the Santen judgment referred to above will impact the future of SPC protection, as it appears to be discriminatory against research into second and further indications. In particular, it is questionable whether this is consistent with the original intentions of the SPC regulations.

Time Frame, Costs, Statistics for Germany

1–4 YEARS

Term Until Grant of a SPC:

Generally, one and a half to four years (depending on the number of office actions and the backlog at the patent office)

Official Filing Fees for the SPC Application:

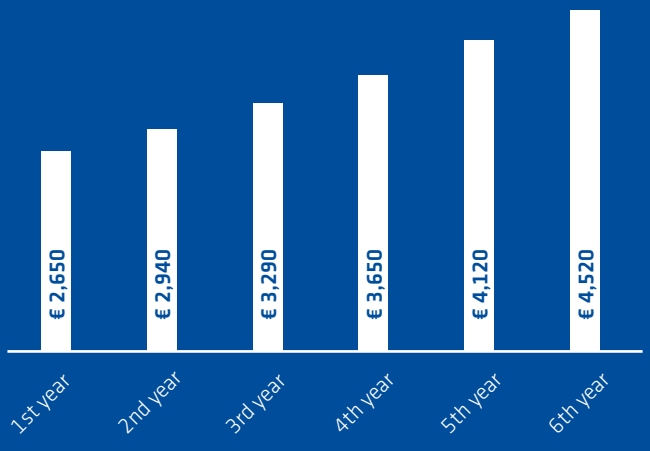
€ 300

Attorney Fees for Filing a SPC Application:

(Depending upon complexity of the case)

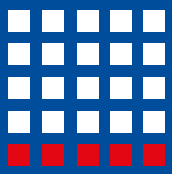
from € 1,200

Official Annual Fees for Maintaining the SPC:

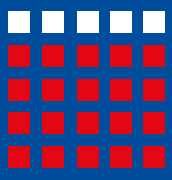


Statistics:

In 2019: 126 SPC applications were published by the German Patent and Trademark Office, 122 thereof were pending or in force on July 26, 2020.



Applications from Domestic Applicants: 25 of the 126 SPC applications were filed by Germany based entities.



Applications from Foreign Applicants: 101 of the 126 SPC applications were filed by foreign based entities, 57 thereof from the USA, 7 from Japan, 0 from China.

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