

Poland

Practical know-how on supplementary protection certificates

Supplementary protection certificates (SPCs) became legal in Poland when it acceded to the European Union on May 1 2004. EU Regulation 1768/92, which regulates SPCs for medicinal products, has been in force in Poland since that date.

EU accession also saw the implementation of two national regulations concerning SPCs:

- Articles 75(1) to 75(10) of the Industrial Property Law; and
- a Regulation of the Prime Minister on lodging and processing applications for a supplementary right of protection for medicinal products and plant protection products (July 29 2003).

EU Regulation 1768/92 uses the term ‘supplementary protection certificate’ to refer both to the supplementary right of protection and the document confirming this grant, whereas Polish law assumes that an SPC refers only to the document confirming the grant of the supplementary right of protection (SPR), an exclusive right. Similarly, a ‘patent’ is defined as an exclusive right for an invention, whereas a ‘letters patent’ is the document confirming the grant of that right. For clarity, throughout this chapter SPC is used within the meaning of EU Regulation 1768/92.

Pursuant to the provisions of the Accession Treaty, Poland was obliged to grant retroactively SPCs for medicinal products that received their first market authorisation after January 1 2000, provided that an appropriate application for the SPC was lodged within six months of the accession date. Fifty-six SPC applications were lodged with the Polish Patent Office (PPO) during this transitional period. However, the related authorisations did not appear to be consistent with the directives mentioned in EU Regulation 1768/92. The PPO therefore adopted the position that a strict interpretation of Article 3b (a transitional regulation) should not be applied; otherwise it would not be possible to grant any SPC for any product that received its first market authorisation between January 1 2000 and May 1

2004. According to the PPO, it is necessary to take into account the purpose of the transitional regulation for SPC applications made during the transitional period. Therefore, the PPO has assumed that authorisations issued by a competent national drug registration agency acting in accordance with the law in force at the time satisfy the requirements of this transitional regulation.

Since January 27 2007, EU Regulation 1901/2006 on medicinal products for paediatric use has also been in force in Poland. This regulation provides for an additional six-month extension of SPCs in specific cases.

Thus, under regulations currently in force in Poland, an SPC may extend the protection conferred by a patent by up to five years and market exclusivity by 15 years; in certain circumstances the certificate may be extended additionally for another six months.

SPCs – subject, scope and premises for grant

Within the scope of a basic patent, the subject of an SPC is the product covered by the authorisation to place it on the market, including any use of the product as a medicinal product that was authorised before the certificate’s expiry. The ‘basic patent’ means the patent protecting the product itself, a method for obtaining the product or an application of the product. The SPC is granted for a compound defined by the international non-proprietary name and, optionally, its salts or esters, provided that these are covered by the subject matter of the basic patent and have the same therapeutic properties as the product that has received market authorisation.

To obtain an SPC, the following conditions must be met in Poland when the SPC application is filed:

- The product must be protected by a valid patent;
- The product must have been issued with a valid market authorisation;
- The product cannot already have been the subject of an SPC; and
- The authorisation must be the first authorisation to place the product on the market as a medicinal product.

When it acceded to the European Union, Poland became subject to the EU centralised regime for the registration of drugs. Thus, neither a separate national registration procedure nor a separate national market authorisation is currently required. However, any SPC application must be accompanied by a Polish translation of all documents confirming the centralised registration and describing the product's characteristics.

Entitlement to lodge an SPC application

Only a patent holder or its successor in title may file an application for an SPC. No third parties are entitled to apply for or obtain an SPC, even if the patent holder issues relevant consent.

If a product is protected by more than one patent held by different proprietors, an SPC may be granted to each of these proprietors, provided that only one SPC is granted per patent. However, if the same product is the subject of several market authorisations of the same date, copies of all these must be filed.

Application for an SPC

An SPC is granted upon filing an appropriate application with the PPO. Applications must be filed within six months of a product receiving market authorisation, or within six months of the patent being granted if the market authorisation was issued before the patent's grant.

The SPC application must include the following:

- a title defining the product (ie, the active substance) in accordance with the international non-proprietary name;
- the applicant's name and address;
- the name and address of the representative, if appointed;
- a request for the grant of an SPR;
- the number of the basic patent and title of the invention;
- the number and date of the first market authorisation; and
- if this market authorisation is not the first, the number and date of the first EU authorisation.

The application must be accompanied by:

- a copy of the first authorisation to place the product on the market (in Poland), containing the date and number of the authorisation, and the product's characteristics;
- a statement on the identity of the product thus authorised and the product of the basic patent if the authorisation is not the first in the European Union (the product, whether an active substance

or a mixture of active substances, shall be the same as in the basic patent);

- a copy of the notice publishing the authorisation in the appropriate official publication, with the legal provision under which the authorisation procedure took place; and
- power of attorney, if necessary.

If the first market authorisation was issued outside the European Union, there is no need to file a copy of this.

Notification about filing an SPC application is published in the official gazette – *Wiadomości Urzędu Patentowego*, also available from the PPO website (www.uprp.pl) – and is recorded in the Patent Register. After the filing of the SPC application is officially announced, third parties may lodge observations.

Examination of the SPC application

SPC applications are examined in two stages. The first stage is the formal examination, where the PPO verifies whether the application has been filed in due time, whether the basic patent is in force and whether the documentation is complete. The PPO also checks whether the required fees for filing the application have been paid and power of attorney granted (if necessary). If anything is missing, the applicant must supplement or correct the documentation within an appointed time, usually two months, or risk having the application rejected.

The second stage is a substantive examination.

The PPO verifies whether the SPC application is for the same product as is covered in Poland by the market authorisation and the patent, at the date of filing. Active salts or esters may be deemed to be covered by the patent's subject matter, even though they are not mentioned as such, provided that they are well known and commonly used in the field of food and/or drug technology and exert the same therapeutic properties as the compounds that are the subject matter of the basic patent. The applicant may be required to submit information confirming that the indicated basic patent protects the product under examination. Then, the PPO examines whether the authorisation is still in force and whether the product has been the subject of an SPC in Poland. The PPO may also check whether the issue dates of the market authorisations are correct. Further, the PPO may examine whether the requirements of Articles 3(c) and (d) of EU Regulation 1678/92 have been fulfilled. If the PPO considers the active substance to be known, the applicant may be required to confirm whether the market authorisation is the first authorisation to place the product on the EU market. Further, the PPO may raise objections concerning the

“ An SPC may be declared invalid if the patent on which it is based is declared partially invalid. If the patent is declared invalid in whole, the SPC becomes invalid automatically ”

fulfilment of requirements for grant of an SPC based on arguments put forward by third parties. If the PPO finds obstacles to the SPC grant, an official communication is sent to the applicant and a deadline for responses is set.

If, despite the applicant's arguments, the PPO finds that the application or the corresponding product fails to meet the necessary requirements for an SPC, the PPO will refuse to grant the SPC. In such cases the applicant is entitled to file a request for the case to be re-examined by the PPO. If the PPO maintains its decision, the applicant may file a complaint with the Administrative Court, and finally, if necessary, a complaint to the Supreme Administrative Court.

If the PPO decides that the application and the corresponding product fulfil the requirements for grant of an SPC, it will issue a decision to grant the SPR and an SPC (as confirmation of the right granted).

Notification of the PPO's decision is published in *Wiadomości Urzędu Patentowego* and is recorded in the Patent Register.

Certificate

SPCs show the following information:

- the rights holder's name and address;
- the number of the basic patent and the title of the invention;
- the number and date of the authorisation(s) and the name of the issuing authority;
- a description of the product;
- the duration of the SPR; and
- a copy of the first authorisation.

A copy of the certificate is available for public inspection at the office's library; however, the certificate as such is not published.

Annual fees

To maintain the SPC, it is necessary to pay annual fees. The current fee for each year of supplementary protection is PLN6,000. The fees for subsequent protection periods may be paid in advance up to one year before the due date, but no later than the expiry date of the preceding protection period. These fees may be reimbursed if the SPC is invalidated or lapses before this time limit. Fees may be paid within six months of the due date but such late fees are subject to a 30 per cent surcharge. The PPO does not send any reminders for the due dates of the annual fees.

Effects of grant

The SPC extends the protection conferred by a patent beyond the 20-year duration of the patent, but only for products covered by a market authorisation. Thus, an SPC confers the same rights and obligations as a patent, and is also subject to the same limitations. The SPC may be assigned to another entity or may be charged with a third party's proprietary right (eg, pledge on right). It may also be a subject to a licence, including open or compulsory licences.

Lapse and/or invalidity

SPCs can lapse under the following circumstances:

- The effective period expires;
- The rights holder surrenders it;
- The annual fees have not been paid in time; or
- The product's market authorisation has been withdrawn after the patent expired.

If the patent lapses, or the authorisation is withdrawn or the SPC holder surrenders it, a decision on whether the SPC has lapsed is issued. Any lapse of

an SPC or decision on a lapse is published in *Wiadomości Urzędu Patentowego* and recorded in the Patent Register.

An SPC may be declared invalid if it was granted contrary to the provisions of Article 3 of EU Regulation 1768/98 and a request for invalidation is filed with the PPO. The invalidation request may be filed by anyone; there is no need for the filer to prove any legal interest. The president of the PPO or attorney general may also file such a request in the public interest or may join ongoing invalidation proceedings. Moreover, an SPC may be declared invalid if the patent on which it is based is declared partially invalid. If the patent is declared invalid in whole, the SPC becomes invalid automatically. The invalidation of the SPC is announced in *Wiadomości Urzędu Patentowego* and recorded in the Patent Register.

Summary

This chapter does not attempt to cover all aspects of the

procedure before the PPO relating to SPCs for medicinal products. Rather, it presents an overview of the main practical issues that are specific to Poland. The SPC regulations have been in force in Poland for five years. During that period 136 applications for SPCs have been lodged with the PPO, 56 of which were made in the transitional period between May 1 2004 and October 31 2004. By mid-2009 the PPO had granted approximately 24 SPCs and this number is likely to increase. The SPC, which basically extends the effective period of protection by up to five years and, under special circumstances, by an additional six months, is important not only for manufacturers of innovative drugs, but also for generic drug manufacturers and society as a whole. Therefore, knowledge of the procedures relating to SPCs is of growing importance to all industry practitioners.



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