Supplementary Protection Certificate (SPC) in Poland - basic regulations

Rafał Witek

WTS Rzecznicy Patentowi - Witek, Czernicki, Śnieżko – spółka partnerska

ul. Rudolfa Weigla 12, 53-114 Wrocław, fax. (+4871) 3467430, tel. (+4871) 3467432, witek@wtspatent.pl

The main reason for introduction of the SPC into Polish legal system are the obligations associated with Poland joining into European Union. Treaty of Accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia to European Union (Treaty of Accession) approved in Poland in autumn 2003 is the most important legal act regulating this historical event. According to the part concerning the SPC included in Annex II of the Treaty of Accession, after our accession to EU the Council Regulation (EEC) No. 1768/92 (CPSC) will be in effect in Poland. Further, it will be only legal act in Poland regulating the Creation of a Supplementary Protection Certificate for Medicinal Products.

In effect of the harmonisation of the Polish Law with the European Law, being the part of our preparation to Accession, one of the last amendments of the Industrial Property Law (in force since October 2002) (Act of 6 June 2002 amending the Act of 30 June 2000 Industrial Property Law – Journal of Laws No 108/2002) introduces the whole chapter 5 (articles 75^{1} to 75^{10}) concerning the SPC (see below).

Chapter 5[1] [1]

Supplementary protection right

Article 75[1]

On the territory of the Republic of Poland supplementary protection rights shall be granted on the conditions laid down in the regulations concerning the creation in the European Union of supplementary protection certificates for medicinal products and plant protection products.

Article 75[2]

1. The application for the grant of a supplementary protection right, hereinafter referred to as "the application", shall be lodged with the Patent Office. The provisions of Article 13(2)-(5) shall apply accordingly.

2. The provisions of Title VI shall apply accordingly to proceedings for the grant of a supplementary protection right.

Article 75[3]

The Patent Office shall make a decision on the grant of a supplementary protection right after having established that the requirements for its grant have been satisfied. The provisions of Articles 42 and 46 shall apply accordingly.

Article 75[4]

1. The grant of a supplementary protection right shall be evidenced by the issue of a supplementary protection certificate. The provision of Article 73 shall apply accordingly.

2. Granted supplementary protection rights shall be recorded in the Patent Register.

Article 75[5]

1. Where the Patent Office finds that the requirements for the grant of a supplementary protection right are not satisfied or that the application has been lodged after the expiry of the prescribed time limit, it shall decide on the refusal to grant the supplementary protection right. The provision of Article 49(2) shall apply accordingly.

2. The term for lodging an application, referred to in paragraph (1) shall not be restorable.

3. The decision on the refusal to grant the supplementary protection right or the decision to discontinue the granting proceeding shall be recorded in the Patent Register.

[1] Added by Article 1 para 7 of the act referred to in footnote 3; it will become effective as from the date of Poland's accession to the European Union

Article 75[6]

1. The Patent Office shall declare the decision on the grant of the supplementary protection right lapsed where:

(i) the basic patent has expired before the termination of the term for which it was granted, or

(ii) during the term of the basic patent the market authorisation for the product has been withdrawn or the right holder has surrendered his supplementary protection right.

2. In the cases referred to in paragraph (1), the granted supplementary protection right shall cease to be valid.

3. The Patent Office shall declare the supplementary protection right lapsed where the authorisation, referred to in paragraph (1)(ii), has been withdrawn after the expiry of the term for which the basic patent was granted.

4. The provisions of Article 90 shall apply accordingly to supplementary protection right.

Article 75[7]

1. Any party may request that the supplementary protection right be invalidated, where:

(i) it has been granted in breach of the provisions governing the requirements for its grant, or

(ii) the basic patent has been invalidated in the part, on which the supplementary protection right has based.

2. The provision of Article 89(2) shall apply accordingly to the cases referred to in paragraph (1).

3. Where the basic patent is invalidated in whole, the granted supplementary protection right shall become invalid by virtue of law.

Article 75[8]

Decisions, declared lapsed, on the grant of the supplementary protection right or on the lapse of that right, or on its invalidation shall be recorded in the Patent Register.

Article 75[9]

1. The provisions governing licence contracts and transfer of the patent shall apply accordingly to the supplementary protection right.

2. The declaration of licenses of the right to exploit the invention, when submitted according to the provisions of Article 80, shall also be effective in respect to the supplementary protection right.

Article 75[10]

The Prime Minister shall, by way of regulation, determine the detailed requirements to be satisfied by an application for the grant of a supplementary protection right, the detailed rules and procedure to be applied in the course of processing applications including, in particular, the place and the manner of publication of the mention of applications lodged, the manner of making entries in the Patent Register, as well as the information to be contained in the supplementary protection certificate. The requirements to be satisfied by applications may not be determined in such a way as to encumber the applicant with excessive and unreasonable impediments.

However, according to article 4 of the same amendment of the Polish Industrial Property Law, the articles concerning SPC will be in force only after Poland has become a member of the European Union. Therefore, filing of the SPC Application to the Polish Patent Office (PPO) will be possible only after this date (probably May 1, 2004). In fact, the introduced regulations create direct reference to application of the appropriate European Law (i.e. Regulation 1768/92) and repeat and fulfil completely the ruling included in Treaty of Accession.

Both Annex II of Accession Treaty as well as the a.m. amendments of the Polish Industrial Property Law include also the transitory regulations concerning the products registered short before Accession. Namely, in Article 2 of the same Act it has been stipulated, that for medicaments approved after 1st January 2000 and before our accession to EU the application may be filed by the PPO until the end of the sixth month of our membership in EU.

Article 2

(Act of 6 June 2002 amending the Act of 30 June 2000 Industrial Property Law – Polish Journal of Laws No 108/2002)

1. *A supplementary protection right may be granted for an active ingredient or combination of active ingredients, which at the date of the accession the Republic of Poland to the European Union are protected by a valid basic patent and for which the first authorisation to place them on the market on the territory of the Republic of Poland or of the European Union has been obtained prior to the date of the accession of the Republic of Poland to the European Union, however no earlier than the date of 1 January 2000.*
2. *Applications for the grant of supplementary protection rights in the cases referred to in paragraph (1) may be lodged within 6 months of the date of the accession of the Republic of Poland to the European Union.*

The same has been stipulated in point (h) Section II of the Annex II of the Accession Treaty introducing the new wording of the Article 19a of the Regulation No. 1768/92 addressed to Poland.

Article 19a

Additional provisions relating to the enlargement of the Community

Without prejudice to the other provisions of this Regulation the following shall apply:

(h) any medicinal product protected by valid basic patent and for which the firs authorisation to place it on the market as medicinal product was obtained after 1 January 2000 may be granted a certificate in Poland, provided that the application for certificate is lodged within six months starting no later than the date of accession;