

Intellectual Asset Management



Implementation of supplementary patent certificates postponed

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The Patent Act provides that a supplementary patent certificate (SPC) may be granted in the event that a basic patent (ie, a patent granted to an owner to protect a product, process or application) has been granted to a product which requires prior authorisation of the competent governmental body in order to be put on the market.

An SPC takes effect immediately after the expiration of the term of the basic patent. The rights conferred by an SPC shall run for a period equal to the period which elapsed between the date of filing the application for the basic patent and the date of the first authorisation to place the product on the market, minus five years.

The duration of an SPC may not exceed five years from the date on which it takes effect.

An SPC will be granted at the request of the basic patent owner, provided that the following conditions are met:

The product (ie, the active ingredient or the combination of active ingredients) is protected by a basic patent in force;

- Marketing authorisation is granted in Croatia;
- The basic patent has not yet been the subject of an SCP;
- The basic patent application was filed in Croatia after 1st January 1993; and
- The first marketing authorisation was granted after 1st January 2005.

Within the limits of the protection provided by the basic patent, an SPC will extend only to a product that has marketing authorisation, as well as for any use of the product that was granted before the expiration date of the SPC.

An SPC application should be filed with the State Intellectual Property Office (SIPO) within six months of the date of grant of the authorisation to put the product on the market or, if the authorisation was granted before the grant of the basic patent, within six months of the date of publication of the granting of the patent.

An SPC shall lapse on the expiry of the period for which it was granted. However, an SPC shall lapse before the expiry of the period for which it was granted if:

- the SPC holder surrenders it on the day following that on which a certified written declaration of surrender is given to SIPO;
- the annual fee for the maintenance thereof is not paid within the prescribed time limit; or
- the product for which the SPC was granted can no longer be placed on the market as a result of the withdrawal of the authorisation to place it on the market in accordance with a national regulation.

SIPO can rule on the expiry of an SPC *ex officio* or at the request of an interested party.

Further requirements for granted pharmaceutical patents may be imposed upon a request for an SPC or a request for commercialisation.

An SPC application shall be filed with SIPO within six months of the grant of marketing authorisation. If the authorisation was granted before the basic patent, the SPC application must be filed with SIPO within six months of the patent publication.

The rights acquired under an SPC shall run from the date of the basic patent application until the grant of the first marketing authorisation. The term of an SPC cannot exceed five years from the date on which it came into force.

Example – calculation of duration of SPC	
Filing date of the basic patent	5th October 1992
First EU marketing authorisation	5th May 2000
Expiry of the basic patent	5th October 2012
Time period elapsed between 5th October 1992 and 5th May 2000	Seven years and seven months
Duration of SPC	Seven years and seven months minus five years: two years and seven months
Expiry of SPC	5th May 2015

Following negotiations and the broad interpretation of the terms “basic patent” and “product”, SIPO began to take the view that if a patent covered more than one product, more than one SPC should be granted. However, this standpoint was one of the minor discrepancies which has led the European Union to require Croatia to postpone the implementation of the SPC provisions into Croatian law. Unfortunately, the European Union has not indicated how such discrepancies should be dealt with.

The implementation of the SPC provisions included in the recently published Act on Amendments to the Patent Act has been postponed until Croatia's accession to the European Union. This postponement is due to certain complaints regarding IP law which have arisen in the course of accession negotiations.

The SPC provisions are expected to be fully harmonised with EU legislation and practice. In addition, the SIPO Guidelines for Patent Search and Examination were drafted and reviewed by EPO-mandated members of the drafting committee, so these should pose no problems.