Supplementary Protection Certificates
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Introduction

The maximum duration of a patent is 20 years. However, companies which develop and sell medical products requiring a licence are often prevented from using their patent protection for a long period of time because of the lengthy process involved in obtaining a licence. As a consequence, special legislation has been drawn up for the pharmaceutical industry in the form of the Regulation on supplementary protection certificates. The Regulation provides for the extension of patent protection by up to five years for a product for which a licence has been obtained.
Subject to certain conditions, a patent owner can even obtain a supplementary protection certificate based on a foreign licence. In the case of a paediatric (children’s medical) application, if data is available, up to a further six months may be granted, subject to certain conditions.

Supplementary protection certificates can be obtained in almost every country in Europe, the USA, Japan, and in numerous other countries worldwide. The respective regulations vary considerably from country to country.

Since many medical products only start to bring significant financial reward towards the end of the patent’s duration, supplementary protection certificates represent an important means of protecting pharmaceutical innovations against imitation.

1. Duration

The duration of a supplementary protection certificate is determined on the basis of the period of time between the registration of the basic patent and the granting of the first licence for the product within the European Community. Five years are deducted from that period of time. If, for example, there is a period of ten years between the registration date and the date of issue of the licence, the supplementary certificate will be valid for five years. A period longer than ten years does not affect the length of time a supplementary certificate can be valid as this is limited by the regulation to a maximum of five years.
2. Product definition

A supplementary protection certificate is issued for a product, in other words a substance. Changes to its medical application (indication), galenic preparation, the species (animal or human) for which it is intended as a treatment, or its pharmacological effectiveness or safety do not constitute the existence of two different products within the meaning of the Regulation.

Basically, derivatives such as salts or ester from a product are included in the scope of a supplementary protection certificate. If the derivative is protected by its own patent, however, a supplementary protection certificate may still be issued for it, subject to certain conditions, even if a certificate has already been issued for the original product.

3. A maximum of one supplementary protection certificate per product per applicant

Each applicant, irrespective of the number of basic patents he may have, can only be issued with one supplementary protection certificate per product. If several applicants have several basic patents, a supplementary protection certificate may be issued to each applicant.

4. Applicant only requires his own basic patent, not his own licence

The requirement for the issue of a supplementary protection certificate is possession of a patent, not a licence. In certain circumstances, an application for supplementary protection can even be based on a foreign licence; this is possible even if it is contrary to the wishes of the licence owner.
5. Time limits for application

An application for a supplementary protection certificate can be made within six months of the issue of the patent or, if issued later, of the licence. This fact alone highlights how important it is for companies to have well coordinated patent and licensing departments.

6. Effect of a supplementary protection certificate

Supplementary protection certificates can basically be used in the same way as patents: the owner can forbid any third party from using the protected product, and infringements can be pursued through the courts. On the other hand, invalidation proceedings may be brought against a supplementary protection certificate.

The supplementary protection certificate is issued in accordance with the category of the underlying patent: if the basic patent is a patent for a material substance, the supplementary protection certificate likewise protects the substance; if a process is protected by the basic patent, the protection of supplementary protection certificate likewise only covers the process; if, finally, the basic patent protects an application, then the protection afforded by the supplementary protection certificate likewise only applies to the application.

The regulatory requirements for supplementary protection certificates need to be given careful consideration as early as the planning and design stage of both patent and licence portfolios.
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