

## Resume – Supplementary Protection Certificates for Medicinal Products

Nowadays, the pharmaceutical industry plays an important role in the world's economy and the pharmaceutical research has a decisive impact on the continuing improvement in public health.

The system of patent law is of cardinal significance to the industry because it confers monopolies, for a limited period of time, on using innovations and provides a crucial incentive for basic research activities. Innovative companies require the guaranteed period of market exclusivity afforded by patents in order to sustain drug prices, recoup research and development expenditures and finance the development of new products. Although the availability of a patent protection for chemical and pharmaceutical products has, from a historical perspective, only been reaffirmed in the near past, it has been widely accepted as a global standard mainly through the provisions of the WTO's TRIPS agreement. On the other hand, despite the existence of various international treaties harmonising patent laws, patents have to date in their effects remained strictly limited to individual jurisdictions.

Closely bound to the patent system itself are the means of the so-called off-patent protection – supplementary protection certificates and the others, for example market exclusivity granted to drugs for orphan diseases.

Supplementary protection certificates are a juridical institute which is designed for pharmaceuticals, especially those that are the result of long, costly research. The period that elapses between the filing of an application for a new medicinal product patent and the authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research. This situation leads to a lack of protection which penalises pharmaceutical research.

European Community introduce an uniform solution in its regulation which should prevent the heterogeneous development of national laws leading to further disparities. Among other topics, the relationship of the basic patent and supplementary protection certificates, the appropriate length of effective duration, the possibility of an extension for paediatric products, and few aspects of the national proceedings are discussed. Finally, this paper mentions several judgments of the European Court of Justice.

Despite all legal aspects we should always keep in mind that the main goal of pharmaceutical industry is to ensure an access to available medicaments for all people.