A QUICK GUIDE TO EU SUPPLEMENTARY PROTECTION CERTIFICATES

In this quick guide to EU Supplementary Protection Certificates (SPCs), we cover the main points relating to SPCs and how to use them.

Q: What are SPCs?

A: SPCs are an IP right that serve as an extension to a patent right. They apply to specific pharmaceutical and plant protection products that have been authorised by regulatory authorities.

Q: What are SPCs used for?

A: The purpose of SPC legislation is to create patent-like sui generis rights, compensating patent holders for the time loss experienced in two sensitive technological fields where new products are subject to extensive regulatory procedures prior to commercialisation.

Q: How did SPCs come about?

A: By establishing common standards, the EU legislature sought to prevent the emergence of diverging national legislation, so as to safeguard the integrity of the internal market.

The SPC Regulations were also aimed at preserving the competitiveness of Europe as an attractive location for pharmaceutical and plant protection-related research.

At the time SPC Regulations were introduced, other jurisdictions, such as the US and Japan, had already enacted legislation providing for an extension of the patent term, inter alia, in the pharmaceutical field.

Q: How are SPCs distinct from other IP rights?

A: Although SPCs conform in many ways to patents and are therefore generally recognised as a form of intellectual property (IP), they are clearly distinct from other IP rights.

Firstly, SPCs are of a hybrid nature; their grant is contingent on the existence of a basic patent and of a marketing authorisation (MA) covering the product.

Secondly, SPCs are based on the Regulations, i.e. on Union law with direct effect throughout the EU; however, Union trade marks and Community designs are not unitary titles of protection.

Under the current system, SPCs are national, territorially restricted rights granted by national offices.

Both features, that is, the hybrid nature of SPCs and their construction as national rights based on an act of Union law, contribute to the fact that SPCs are quite unique, both within the EU and internationally.

Q: How long can an SPC extend a patent right?

A: An EU SPC can extend a patent right for a maximum of five years.

A six-month additional extension is available in accordance with Regulation (EC) No 1901/2006 if the SPC relates to a medicinal product for children for which data has been submitted according to a Paediatric Investigation Plan (PIP). PIPs are required to support the authorisation of medicines for children.

Q: How will SPCs be affected by the European Unitary Patent?

A: The 'patent package' that lays the ground for the creation of unitary patent protection in the EU does not explicitly provide for a 'unitary SPC'.

To ensure that companies who choose unitary patent protection can benefit from the SPC extension, the European Commission is working on the articulation of unitary patent protection and SPC legislation.

Q: Have there been any other recent developments regarding SPCs?

A: On 28 May 2018, the Commission adopted a proposal for a regulation to amend Regulation (EC) No. 469/2009 on supplementary protection certificates for medicinal products.

This initiative proposes to introduce an exception to let EU firms manufacture certain pharmaceuticals for export to non-EU markets during the term of the SPC.

FOR FURTHER INFORMATION

Please contact **Dr Russell Thom**, **Anne Marie Carr** or **Dr Marina Mauro** for any further questions you might have in the area of SPCs.

Dr Russell Thom
Director, Patents
(Head of Chemistry Practice)

Glasgow, UK
T. +44 (0)141 307 8400
E. russell.thom@murgitroyd.com

Anne Marie Carr
Director, Patents

Dublin, Ireland
T. +353 (0)1 882 9400
E.anne-marie.carr@murgitroyd.com

Dr Marina Mauro
Senior Patent Attorney

Milan, Italy
T. +39 (0)2 87 39 85 63
E. marina.mauro@murgitroyd.com