



BRISTOWS

Fordham IP
Conference 2013

Supplementary
Protection Certificates

Introduction

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SPCs – Basic Concepts and Definitions

- SPC regime introduced in Europe in 1992 to provide partial compensation to patent holders in the pharmaceutical field for the patent life lost in obtaining regulatory approval
- The SPC regime was deemed necessary to encourage pharmaceutical research and development in Europe; and to keep up with the USA and Japan which introduced similar regimes in the 1980s
- Original Regulation 1768/92 was codified and consolidated into Regulation 469/2009
- A “uniform solution” is contemplated...

SPCs – Basic Concepts and Definitions

Three key definitions:

Basic patent: a patent protecting: (i) a product as such; (ii) a process or (iii) an application for a product

Product: the active ingredient or combination of active ingredients of a medicinal product

Medicinal Product: the substance presented for treating or preventing disease in humans



SPCs Conditions for Obtaining a Certificate (Article 3)

- (a) the **product is protected by a basic patent** in force;*
- (b) a **valid authorisation** to place the product on the market as a medicinal product has been granted **in accordance with Directive 2001/83/EC** or Directive 2001/82/EC, as appropriate;*
- (c) the product has **not already been the subject of a certificate**;*
- (d) the authorisation referred to in point (b) is the **first authorisation to place the product on the market as a medicinal product.***
(Emphasis added)

The Medeva / Queensland / Georgetown / Daiichi references

- Where there is a patent claiming A; and an MA for A&B, can an SPC for A&B be obtained?
- In other words, is A&B “protected by a basic patent” for A?

Medeva question:

What is meant by “the product is protected by a basic patent in force” and what are the criteria for deciding this?

Medeva answer:

Article 3(a) must be interpreted as precluding the grant of an SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on.



Thank you for your attention

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