Supplementary Protection Certificates

Combination therapies
Earlier MA for different indication

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Supplementary Protection Certificates

- Creature of EU law – Regulation 469/2009
- Effect is to extend term of protection by up to 5 years
- Application for SPC must be made within the earlier of 6 months of marketing authorisation in a member state or 6 months of grant of patent
- Grant of SPCs administered by national patent offices
- National courts of EU members states refer questions of EU law for determination by the Court of Justice of the European Union
- Decisions of the CJEU often require further elucidation, leading to multiple references by national courts
Regulation 469/2009

Article 1 - Definitions

(a) ‘medicinal product’ means any substance or combination of substances presented for treating or preventing disease in human beings or animals …

(b) ‘product’ means the active ingredient or combination of active ingredients of a medicinal product

(c) ‘basic patent’ means a patent which protects a product as defined in (b) as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate
Regulation 469/2009

Article 3 – Conditions for obtaining a certificate

A certificate shall be granted if … at the date of the application:

(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/EEC or Directive 2001/82/EEC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in (b) is the first authorisation to place the product on the market as a medicinal product
Regulation 469/2009

Article 4 – Subject-matter of protection

Within the limits of protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

Article 5 – Effects of the certificate

Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.
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• So what happens if the patent claims A but the marketing authorisation is for A+B?

• Or if the patent claims A+B but the marketing authorisation is for A+B+C+D?

• Or if the patent claims A+B but the marketing authorisation is for A?

• Specifically, does “product” in Articles 3(a) and (b) have to be interpreted in the same way?
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*Medeva BV v Comptroller General of Patents, Designs and Trade Marks*

- Medeva’s patent claim covered the use of two antigens of the whooping cough pathogen in combination as a vaccine (pertactin and filamentous haemagglutinin (FHA))

- This combination was not marketed alone but in combination with other vaccines against diphtheria and tetanus or against these and also meningitis and polio

- The relevant marketing authorisations all related to these larger combinations

- Medeva applied for SPCs in respect of the medicinal products the subject of the authorisations – should they be allowed?
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Article 3(a) – the product is protected by a basic patent in force

Key question – how should this be determined?

• “infringement” test

or

• “scope of protection” test
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Medeva – CJEU decision (24 November 2011)

• Article 3(a) … must be interpreted as precluding the [grant of] a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the [SPC] application

• Article 3(b) … does not preclude the [grant of] a SPC for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the application for a SPC contains not only that combination of the two active ingredients but also other active ingredients
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Related references to CJEU

• *Georgetown* – same decision given at same time as *Medeva*

• *Daiichi (C-6/11)* – reasoned order: same ruling as *Medeva*, save answer referred to “identified” rather than “specified”

• *Yeda (C-518/10)* – reasoned order: no SPC for active ingredient (alone) where the active ingredient only claimed in combination with another active
Process claims

*University of Queensland (C-630/10) – CJEU reasoned order*

- University had patent family covering (i) A or B, (ii) C, (iii) D, and MA’s for A+B+C+D and C+D. CJEU followed *Medeva* reasoning.

- Parent patent also had a process claim covering a method of production of A or B basic patent relating to process by which ‘product’ made

- Held: “... just as Article 3(a) precludes the grant of a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent, ... that provision also precludes a SPC being granted for a product other than that identified in the wording of the claims of that patent as the product deriving from that process. ... Whether it is possible to obtain the product directly as a result of that process is irrelevant in that regard.”
Earlier MA for different indication

- **Neurim Pharmaceuticals**

- *Article 3(d)* - the authorisation referred to in (b) is the first authorisation to place the product on the market as a medicinal product

- Neurim’s patent covered formulations of melatonin that could be used to treat insomnia – no suggestion that the claims were not novel & inventive

- Neurim’s MA for Circadin took 15 years to obtain due to full regulatory testing being required – SPC applied for in respect of this MA

- IPO objected to grant of SPC on basis of an earlier MA for melatonin for use in sheep, to regulate their seasonal breeding activity

- IPO’s decision upheld by High Court; matter referred to CJEU by Court of Appeal
Earlier MA for different indication

Neurim Pharmaceuticals – Advocate General’s Opinion (3 May 2012)

• Same AG as in Medeva (Verica Trstenjak)

• The fact that the same product has previously been authorised as a medicinal product for human use or a veterinary medicinal product in the Member State for which the application is made does not preclude the grant of a supplementary protection certificate based on a later authorisation to place that product on the market as a new medicinal product, provided the first-authorised medicinal product is not within the scope of protection conferred by the patent designated by the applicant as the basic patent.

• The first authorisation to place the product on the market in the EU … must also be understood as the first authorisation to place a product on the market in the EU as a medicinal product which is within the scope of protection conferred by the basic patent designated by the applicant.
Earlier MA for different indication

*Neurim Pharmaceuticals – CJEU judgment* (19 July 2012)

• Fundamental objective of the SPC Regulation is to ensure sufficient protection to encourage pharmaceutical research

• Articles 3 and 4 … must be interpreted as meaning that, in a case such as that in the main proceedings, the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate.
SPCs – what next?

• Decisions confirm the teleological or purposive approach to the interpretation and application of EU law

• Neurim effectively confirms that a new use of an active ingredient can be eligible for an SPC.

• Will undoubtedly be – and have been – further references to CJEU

• What is meant by “specified/identified in the wording of the claims”? e.g. express naming, identification through description, necessary implication, reasonable interpretation (Medeva, Court of Appeal, 3 May 2012) – UK Actavis reference

• Scope of protection – salts, enantiomers (Lundbeck reference)

• Can more than one SPC be granted in respect of each basic patent? (Biogen says yes, but AG Trstenjak’s opinions indicate no). Question referred to CJEU by both Dutch (Georgetown University) and UK (Actavis) courts.
Thank you

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