

An Update on SPCs

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Background

- SPC Regulation 469/2009
 - Purpose is to extend 20-year term of patent protection to compensate for delays in obtaining regulatory approval for medicinal products
- SPC Duration
 - The time between grant of first authorisation and the patent filing date, minus 5 years, to a maximum of 5 years.

Conditions for Obtaining an SPC (Art. 3)

- A certificate shall be granted if, in the Member State in which the application is submitted and at the date of application:
 - (a) the product is protected by a basic patent;
 - (b) a valid authorisation to place the product on the market as a medicinal product has been granted;
 - (c) the product has not already been the subject of a certificate;
 - (d) the authorisation (b) is the first authorisation to put the product on the market.

Important Definitions (Art. 1)

- “Medicinal Product” means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals.
- “Product” means the active ingredient or combination of active ingredients of a medicinal product.
 - “Product” does not include non-therapeutic substances (MIT, C-431/04) or therapeutic use (Yissum, C-202/05)
- “Basic Patent” means a patent which protects a product 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 grant of an SPC.

SPCs for Combination Products

- Can I get an SPC if patent claims A, but authorized product is A + B?
 - Medeva (C-322/10) and Georgetown (C-422/10), now conjoined
 - multi-disease vaccines
 - Yeda Research & Development Company (C-518/10)
 - combination of antibody (Erbitux) and cytotoxic drug (Irinotecan)
 - University of Queensland/CSL (C-630/10)
 - HPV multivalent vaccine
 - Daiichi Sankyo Company (C-6/11)
 - Combination product for hypertension treatment

MEDEVA – Summary of Facts

- Patent claims two whooping cough antigens (A + B)
- Marketing Authorisation (MA) for a vaccine including these two antigens and antigens for other diseases (A + B + C + D)

Can Medeva get an SPC?

- Medeva applied for an SPC for A + B + C + D
 - Is A + B + C + D protected by the patent?
- Medeva argued an infringement test should be applied
 - A + B + C + D would infringe claims due to presence of A + B, so it's protected.
- UKIPO and Patents Court said no and refused SPC (applying *Takeda*, *Gilead* and *Astellas*).
 - The test for “protected by” is a “disclosure test”. Infringement is not enough.

Can Medeva get an SPC?

- Medeva also applied for an SPC for A + B
- It's “protected”, so Art 3(a) fulfilled
- But, MA did not authorize A + B alone, so not “a valid authorisation to place the product on the market”.

- Literal interpretation of Art 1(b)
 - emphasis on authorization to place the product on the market
 - only combination of all active ingredients is “the product”.
- Rejected infringement test
 - The “protective effect” was distinguished from the “subject matter” of the patent
 - Patent “protects” a product only if the product falls within the “subject matter” of the patent

- What does the “subject matter” test mean?
 - Combination must be expressly claimed?
 - Disclosed in description, regardless of whether claimed?
 - One active claimed “in combination with another active agent”?
- Result is a patent for a subset of active ingredients does not “protect” the product

- Purpose of SPC Regulation was considered
 - Legitimate interest in marketing multi-disease vaccines
 - Against objective of SPC Regulation to prevent SPC protection for such combination products.
- AG's Solution:
 - Interpret “the active ingredient” in Art 1(b) to mean “an active ingredient”.

- Define “the product” to fit the patent
- A MA for a medicinal product which includes “the product” as an active ingredient can be relied on
 - Valid authorisation even if only authorised in combination with other active ingredients
- SPC covers “the product” on its own or in combination with anything else

What does this mean?

- Example:
 - Subject matter of patent is A
 - MA granted with A + B
 - Get SPC for A, which also covers A + B
- Safeguard
 - Only one SPC per product
- Example (cont):
 - Later MA for A + B + C, no further SPC allowed
 - Earlier MA for A could prevent any SPC

CJEU Ruling – 24 November

- "1. Article 3(a) ... must be interpreted as precluding the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate."

- “2. Article 3(b) ... must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a supplementary protection certificate 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 special protection certificate contains not only that combination of the two active ingredients but also other active ingredients”.

- In summary, the test is:

Any active (or combination of actives) that is “specified in the wording of the claims” may be the subject of an SPC, provided the active has been authorised as a medicinal product. This authorisation may be for the active on its own, or in combination with other actives

- Another MA for a further combination comprising the active would not be a “first authorisation” – no further SPC

- Would sale of A + B infringe SPC for A?
 - Comments made by CJEU in relation to SPC conferring the same rights as the basic patent should give more confidence that an SPC for an individual active ingredient will protect against infringing combination products containing the active ingredient.

- What does “specified” mean in “specified in the claims of the patent”?
 - Is specificity required? How specific?
 - Is “in combination with another agent” enough?
- Unlikely to be the end of the story

All Clear Now?

- CJEU also seem to have maintained AG's view that the *Biogen* ECJ judgement is authority for a principle that "only one certificate may be granted for a basic patent"
 - Doesn't address consequences for patent relating to multiple products
 - Whether several SPCs can be granted for different products under the same basic patent is likely to be an area for further dispute

Other SPC Issues

- Zero/Negative term SPCs
 - Important for 6-month paediatric extension
 - If SPC calculation gives you minus 1 month, you could still get 5 months paediatric extension
- Variation across Europe:
 - Negative term granted – e.g. UK, NL
 - Negative term rejected – e.g. PT, SI, DE
 - Zero term granted – e.g. GR
- Referred to CJEU by German Federal Patent Court (Merck, C-125/10)
 - AG Opinion suggests grant of negative term, not a zero term, is the correct approach.

Other SPC Issues

- Can SPC be granted if there's a previous authorization for a different use?
 - Neurim referral to CJEU
 - Earlier MA for melatonin to improve reproductive performance of sheep considered fatal to later application for SPC relying on MA for melatonin to treat insomnia in humans.

Thank you...

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