

**Supplementary Protection Certificates (SPCs)**  
**The scope**

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**Main practical question**

Is a SPC designating the active ingredient A infringed by:

- ▶ a drug containing A + B?
- ▶ a drug containing A' (a variant of A)?

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## Legal question

Is the scope of a SPC designating the active ingredient A:

- ▶ limited to the drugs having A as active ingredient?
- ▶ or comparable to the scope of a patent claiming A?

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## Provisions of Regulation No. 469/2009

- Article 4, « *Subject-matter of protection* »:

« *Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized 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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## Explanatory Memorandum of 11 April 1990

« 43. *The effects of the certificate on the subject to which it refers as described in Article 4 are the same as those of the basic patent.*

*The patent system has hitherto constituted the best tool to encourage research. It is therefore not surprising, in view of the objective of this Regulation, that the certificate grants **the same rights**, subject to the same limitations.*

44. *Consequently, in the case of a basic patent covering a product, **the rights granted by the certificate will be the same as those granted by the patent**, but limited to any use of the product authorized prior to the expiry of the patent.* » <sup>(1)</sup>

## Regulation (EEC) No. 1610/96 concerning SPC for plant protection products


■ Recital (13):

« (13) *Whereas the certificate confers the same rights as those conferred by the basic patent; whereas, consequently, where the basic patent covers an active substance and its various derivatives (salts and esters), **the certificate confers the same protection**; »*

■ Recital (17):


« (17) *Whereas the detailed rules in recitals (...), 13 (...) of this Regulation are also valid, mutatis mutandis, for the interpretation in particular of (...) Article 4 (...) of Council Regulation (EEC) No. 1768/92.* »

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**CJEU, 16 September 1999,  
Farmitalia Carlo Erba (C-392/97)**

« (...) where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, **the supplementary protection certificate is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent.** » (operative part, § 1)


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**One decision in France** <sup>(2)</sup>

- A SPC covering A (Losartan)
- Was found infringed
- By a product containing A + B (Losartan and HCTZ, 2 active ingredients)

 (2) Paris Court of 1st instance, preliminary injunction, 12 February 2010, Du Pont de Nemours / Mylan 8

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## Opposite decisions in Belgium <sup>(3)</sup>



- The paediatric extension of the SPC designating Losartan
- Was found not infringed
- By the drug comprising Losartan and HCTZ
- Because the latter was the subject matter of another SPC with no paediatric extension

VÉRON VA & ASSOCIÉS AVOCATS (3) Brussels commercial Court of 1st instance, 12 February 2010, upheld on 17 February 2010, Du Pont de Nemours / Merck Sharp & Dohme 9

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## SPC: contributory infringement?



Two Italian decisions <sup>(4)</sup> :

A SPC designating a product containing A + B was found infringed by the manufacturing of the active principle A

VÉRON VA & ASSOCIÉS AVOCATS (4) Court of Rome, 4 June 2003, Court of Milan, 17 September 1998 10

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**Infringement of a SPC by the manufacturing  
of the active ingredient formulated abroad**




One Belgium decision,  
20 November 2008,  
CNRS, Pierre Fabre Médicament / Ajinomoto  
Omnichem



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**Thank you**

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