PATENT EXTENSION FOR MEDICINAL PRODUCTS IN EUROPE:
SUPPLEMENTARY PROTECTION CERTIFICATE
SPECIFIC CASE LAW
AND THE EXPORT WAIVER

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What's SPC ?

A supplementary protection certificate (SPC) is an IP right that extends a patent by up to five years for a pharmaceutical or plant product that has been authorised by regulatory authorities. The SPC was established to compensate, at least in part, the time spent between the filing of the Patent Application and the granting of the Marketing Authorization (MA).

LEGAL BASIS

Regulation EC/469/2009 concerning SPCs for medicinal products
Regulation EC/1610/1996 concerning SPCs for plant protection products (Biocides)
Regulation EU/933/2019 concerning amendments that establish the so-called *"SPC waiver"*
Regulation EC/1901/2006 concerning a further six-month additional extension available if the SPC relates to a medicinal product investigated for paediatric use.

Recital 13 Reg. EC/1610/96	Active substance and its derivatives (salts and esters) covered by the same patent	One SPC
Recital 14 Reg. EC/1610/96	Active substance and its derivatives (salts and esters) covered by different patents	Different SPCs
Article 3 (2) Reg. EC/1610/96	Different patents for the same product, but same holder of those patents	One SPC
Article 3 (2) Reg. EC/1610/96	Different patents for the same product and different holders of those patents	Different SPCs

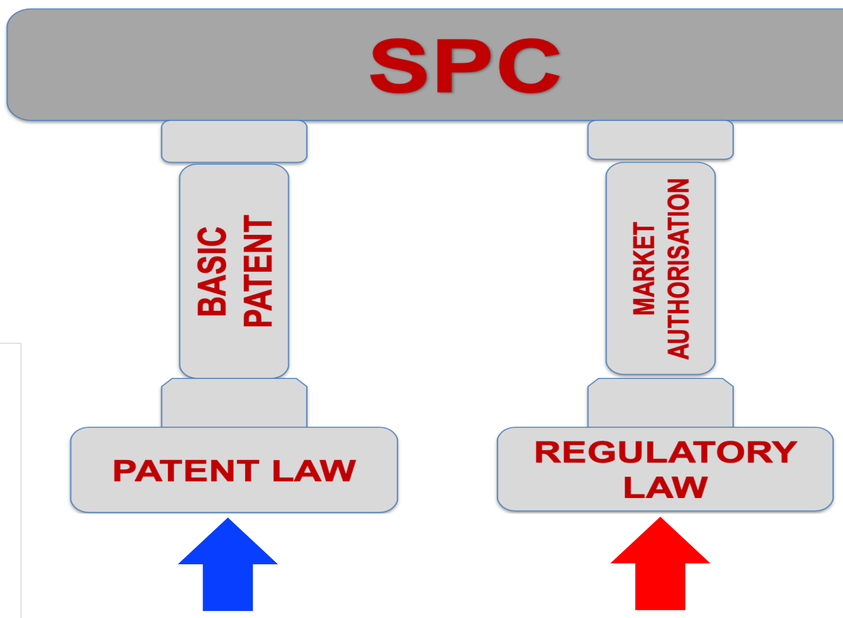
DEFINITIONS

Art.1 Reg. EC/469/2009: *PRODUCT*
Active ingredient or combination of active ingredients of a medicinal product.
Object of SPC

European Court of Justice (CJEU): *PRODUCT*
Should be understood as what the substance becomes in the human body after administration.
The final substance that interacts with the cellular receptor to generate the pharmacological effect.

Art.1 Reg. EC/469/2009: *MEDICINAL PRODUCT*
Medicine ready for use: active principles + eccipients + additives + stabilizers
Object of MA

Sui generis nature of SPC



it's an I.P. *right*
which is based on 2 legal pillars

REGULATION EC/469/2009
SPECIFYING THE CONDITIONS FOR OBTAINING THE SPC

Patent Law — **Art. 3** — **Regulatory Law**

3a) the **product** is protected by a **basic patent in force**

3b) 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

3c) the **product has not already been the subject** of a certificate

3d) the authorisation referred to in point (b) is the first authorization to place the product on the market as a medicinal product

GUIDE FOR SPCs APPLICANTS BY LAW

	PATENT LAW Biocides & Medicinal products		PATENT LAW Medicinal product					REGULATORY LAW Medicinal product	
LAW OF REFERENCES	Recitals 13 and 14 1610/96	Art. 3 (2) 1610/96	Art. 3a 469/2009	Art. 3a 469/2009	Art. 3a 469/2009	Art. 3a 469/2009	Art. 3c 469/2009	Art. 3b 469/2009	Art. 3d 469/2009
OBJECT	Derivatives of active substances (salts and esters)	Product with different patents	Active ingredients not specified in the basic patent	Combination of new active ingredients or one new active ingredient with a second of the prior art	Combination not expressly mentioned in the claims of the basic patent	Active ingredient neither specified in a claim nor identified in the description of the patent	Combination of active ingredients; the patent protects only one of those active ingredients	Single active ingredient or combination The product contains also other active ingredients	Active ingredient that has already been the subject of a MA (different indications or formulations)
APPLICATION FOR SPC	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No
CONDITIONS	Derivatives are covered by a different patent	Different holders of the patents		Corresponding to that specified in the basic patent.	The combination must **necessarily** fall under the invention covered; each active ingredient must be **specifically** identifiable	The claims relate **implicitly** but **necessarily** and **specifically** to the **active ingredient**. The product must not be developed after the filing date of the application for the basic patent	The holder of the patent does not have already an SPC	The **MA** must comprise the same **active ingredient** of the SPC. In case of an SPC for a composition, the MA must contain all the active ingredients	
CHARACTERISATION			Structural	Structural	Structural	Functional			

GUIDE FOR SPCs APPLICANTS BY CASE LAW OF THE CJEU

CASE LAW	Medeva C-322/10	HGS vs Eli Lilly C-493/12	Gilead C-121/17	Royalty Pharma C-650/17	Georgetown C-422/10	Medeva C-322/10	Sanofi C-443/12	Boehringer C-577/13	Abraxis Biosciences vs Comptroller C-443/17	Santen vs INPI C-673/18
LAW OF REFERENCES	Article **3(a)** Regulation EC/469/2009	Article **3(a)** Regulation EC/469/2009	Article **3(a)** Regulation EC/469/2009	Article **3(a)** Regulation EC/469/2009	Article **3(b)** Regulation EC/469/2009	Article **3(b)** Regulation EC/469/2009	Article **3(c)** Regulation EC/469/2009	Article **3(c)** Regulation EC/469/2009	Article **3(d)** Regulation EC/469/2009	Article **3(d)** Regulation EC/469/2009
PRODUCT	Acellular vaccine consisting of **2 active ingredients**: *pertactin and filamentous haemagglutinin*	Composition containing as **active ingredient** the *Ab, Tabalumab, that binds specifically to Neutrokine-α*	**Medicinal product** that contains **2 active ingredients**, *tenofovir disoproxil ('TD') and emtricitabine*	*Sitagliptin, inhibitor of the enzyme DP IV,* which contributes to the regulation of blood sugar levels	*Human papillomavirus (PV) L1 protein* induces antibodies virion-neutralizing	Acellular vaccine consisting of **2 active ingredients**: *pertactin and filamentous haemagglutinin*	Combination of *irbesartan and hydrochloro-thiazide*	Combination of Telmisartand and Hydrochloro-thiazide	Combination of nanoparticles of *paclitaxel* coated with *albumin*	Ophthalmic emulsion with *ciclosporine* as **active ingredient**
ISSUE	SPC related to the **active ingredients which are not specified** in the basic patent claims	SPC related to the **active ingredient** covered by **a *functional formula*** in the basic patent claims	SPC for a **product** composed of **several active ingredient; the combination is not expressly mentioned** in the basic patent claims	SPC for a **product** not specified in a claim nor identified in the description, developed **after the filing date of patent application**	SPC for an **active ingredient;** the **medicinal product contains also other active ingredients**	SPC for **combination of active ingredients**; the **medicinal product contains also other active ingredients**	SPC for **combination of active ingredients**; the patent protects only one active ingredient, for which **the holder of that patent has already an SPC**	SPC for **combination of active ingredients,** the patent originally covered only one active ingredient, for which the holder of that patent has already an SPC. **The claim to the combination has been inserted subsequently**	SPC based on a MA that covers a **new formulation** of an old active ingredient, already been the subject of MA	SPC based on a MA that covers a **new therapeutic application** of an active ingredient that has already been the subject of a MA
GRANTING SPC	PRECLUDED	NOT PRECLUDED IF *	NOT PRECLUDED	PRECLUDED	NOT PRECLUDED	NOT PRECLUDED	PRECLUDED	PRECLUDED	PRECLUDED	PRECLUDED

* If the claims relate, *implicitly but necessarily and specifically*, to the active ingredient in question !!

SPC WAIVER:
REGULATION EU/933/2019

EU export

For the purpose **TO EXPORT** to third countries outside the EU

TO STORE the product in one of the EU countries, but not earlier than six months before the expiry of the SPC

What is the purpose of this waiver to the SPC Regulation?

The waiver will have the effect of creating an exception to the protection conferred by an SPC so as to allow the making of a medicinal product for the purpose of export to third countries outside the EU as well as permitting stockpiling for day-1 entry to the EU market immediately after SPC expiry.

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