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SPCs in Europe: Scope, Challenge, and the Path to Generic Entry

Innovation, Protection, Globalization – A New Ecosystem for Pharma IP

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SUPPLEMENTARY PROTECTION CERTIFICATES IN EUROPE

THE EUROPEAN UNION

27 Member States — the Territorial Framework for SPC Protection

01 Austria

02 Belgium

03 Bulgaria

04 Croatia

05 Cyprus

06 Czechia

07 Denmark

08 Estonia

09 Finland

10 France

11 Germany

12 Greece

13 Hungary

14 Ireland

15 Italy

16 Latvia

17 Lithuania

18 Luxembourg

19 Malta

20 Netherlands

21 Poland

22 Portugal

23 Romania

24 Slovakia

25 Slovenia

26 Spain

27 Sweden



The SPC System in Europe

Regulation (EC) No 469/2009 compensates the effective loss of patent protection caused by the time needed to obtain marketing authorisation for a medicinal product — balancing incentives for pharmaceutical research against timely access to generics and biosimilars.

1

Paediatric Extension

An additional 6 months is added to the SPC duration where the paediatric investigation requirements of Reg. 1901/2006 are satisfied.

2

Bolar Exemption

Permits bioequivalence and clinical studies, and preparation of the regulatory dossier, to be carried out during the term of the patent/SPC without infringing it.

3

Manufacturing Waiver

Reg. (EU) 2019/933 allows EU-based manufacturing during the SPC term for export to third countries where protection does not exist or has ended, and stockpiling in the last 6 months for a “day-1” EU launch.

No Unitary SPC — there is no single EU-wide title. Certificates are applied for, examined and granted separately by the national patent office of each Member State.

Duration of the Certificate and Filing Deadline

Article 13 — Duration of the Certificate

The certificate shall take effect at the end of the lawful term of the basic patent, for a period equal to the period which elapsed between the date on which the application for the basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years. The duration cannot exceed five years from the date on which it takes effect, with a further six-month extension available where the paediatric provisions apply.

SPC duration = (date of first EU/EEA marketing authorisation – filing date of the basic patent) – 5 years — capped at 5 years

Seattle Genetics, C-471/14 — the relevant “date of the first MA” for Article 13 purposes is the date the authorisation decision is notified to its addressee, not the date of the decision itself; the Court required a uniform, EU-wide interpretation of this date.

Article 7 — Time Limit for Filing

The application for a certificate must be lodged within six months of the date on which the marketing authorisation referred to in Article 3(b) was granted. Where that authorisation is granted before the basic patent, the six-month period runs instead from the date the patent was granted.

A procedural rule with substantive consequences: the right to an SPC is lost if the application is not filed in time. In practice, the temporal relationship between grant of the marketing authorisation and grant of the basic patent must be checked carefully in every case.

Articles 1(b) and 3 — Reg. (EC) No 469/2009

Art. 1(b) — Definition of “product”

“Product” means the active ingredient or combination of active ingredients of a medicinal product.

Art. 3 — Conditions for obtaining a certificate

A certificate shall be granted if, in the Member State in which the application is submitted and at the date of that application:

- (a) the product is protected by a basic patent in force;
- (b) a valid marketing authorisation as a medicinal product has been granted for the product;
- (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.



ARTICLE 1(b)

Identifying the “Product”

Definition of “Product” and “Active Ingredient”

MIT, C-431/04 (pt. 18, 19)

An active ingredient is a substance producing an action of its own on the body. Minor changes — a new dosage, a different salt/ester, or a different pharmaceutical form — do not create a new “product” and will not lead to the issue of a new SPC.

Yissum, C-202/05 (pt. 17, 19)

The notion of “product” must be construed strictly, as the active substance itself; a new medical use for the same active ingredient does not create a new product.

GlaxoSmithKline, C-210/13

An adjuvant that reinforces the therapeutic effect of an antigen in a vaccine, but has no therapeutic effect of its own, is not an “active ingredient.”

Forsgren, C-631/13 (pt. 25)

“Active ingredient” means a substance producing a pharmacological, immunological or metabolic action of its own on the organism.

ARTICLE 1(B)

New Formulations, New Uses & Combinations

Santen, C-673/18 (pt. 47)

A known active ingredient (or combination) intended for a different therapeutic application cannot be regarded as a distinct “product.”

Diverse application ≠ new product.

Abraxis, C-443/17 (pt. 31)

A new formulation (e.g. nanoparticles bound to a carrier such as albumin) is not a different product where the carrier has no therapeutic effect of its own — even if efficacy improves.

Greater efficacy ≠ new product.

GlaxoSmithKline, C-210/13

For a “combination of active ingredients,” each component must possess therapeutic properties of its own. Pairing an active substance with a non-therapeutic carrier or adjuvant does not qualify as a “composition of active ingredients”

Forsgren, C-631/13 (pt. 53)

A covalently-bound carrier protein (e.g. conjugated to a polysaccharide antigen) qualifies as an “active ingredient” only if it shows a pharmacological effect of its own within the authorised indications listed in the marketing authorization.

ARTICLE 3(a)

the product is protected by a basic patent in force

Basic patent

“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 the procedure for grant of a certificate

ARTICLE 3(A)

Meaning of “protected”

Evolution of EU case law: From Medeva to Royalty Pharma



Rejects the mere infringement test;
requires specific identification of
the active ingredient in the claims.

Functional claim language is
admissible, provided it implicitly
and necessarily relates to the
product.

Establishes a two-step test:
technical necessity and specific
identification (see next slide).

Excludes products developed after
the filing date through an
autonomous, later inventive step,
even if such products are included
within a functional definition
contained in the claims.

ARTICLE 3(A)

The “Teva” Two-Step Test & Combinations (A+B)

STEP 1 — Technical Necessity (C-121/17, pt. 48–49)

The skilled person, in light of the description and drawings, must understand unequivocally that the product is a feature necessary for the solution of the technical problem disclosed by the patent.

STEP 2 — Specific Identification (C-121/17, pt. 51–52)

Even if not expressly named in the claims, the product must be specifically identifiable by the skilled person, in light of all the elements disclosed by the patent and the state of the art at the filing or priority date.

COMBINATIONS (A+B) — Teva/MSD & Clonmel, C-119/22 and C-149/22 (pt. 69–70)

If component B is public knowledge, the combination A+B is protected only where the patent discloses that the combination itself is a feature necessary for solving the technical problem — for example by showing a combined (synergistic) effect going beyond the mere addition of the individual effects. Explicit mention of A+B in the claims is not, by itself, sufficient.

ARTICLE 3(b)

a valid marketing authorisation as a medicinal product has been granted for the product

Product vs. Medicinal Product

The SPC protects the “product” — not the marketed medicinal product as a whole. (Medeva, C-322/10, pt. 37)

Medeva, C-322/10 · Georgetown, C-422/10

A certificate may be granted for an active ingredient (or combination) claimed by the patent even where the authorised medicinal product also contains further, unclaimed active ingredients.

Forsgren, C-631/13

Art. 3(b) precludes the grant of an SPC where the therapeutic effect of the active ingredient is not covered by the therapeutic indications authorised in the MA.

Situation	Outcome	Reference
MA contains fewer active ingredients than the patent	✗	Medeva pt. 26 · Yeda, C-518/10
MA contains more active ingredients than the patent	✓	Medeva · Georgetown, C-422/10
Therapeutic effect not stated in the MA	✗	Forsgren, C-631/13
MA contains a single active ingredient authorised “for use in combination with” another active ingredient	?	Pending — C-456/24

ARTICLE 3(c)

the product has not already been the subject of a certificate

ARTICLE 3(C)

Multiple Proprietors, Multiple Products, Combinations

Purpose: prevent the maximum protection period per product (Art. 13) from being exceeded — not to prevent every duplication of protection.

Different titleholders, same product — Biogen, C-181/95 · AHP Manufacturing, C-482/07

Two holders of different basic patents may each obtain their own SPC for the same product, independently of one another's consent.

Same patent, multiple distinct products, one MA for the combination — Georgetown University, C-484/12

Where a patent protects a combination (A+B) and its individual components (A) and (B) as such, separate SPCs may be granted for each “product” if individually protected by the basic patent (Art 3(a) TEVA's two-step test needs to be satisfied for the combination and each individual products).

Example: the HPV (human Papilloma Virus) vaccine Gardasil®: SPCs were granted both for the antigen combination and for individual antigens; the MA was for the combination

Same patent, multiple distinct products, two MAs — Actavis v Sanofi, C-443/12 · Actavis v Boehringer, C-577/13 · clarified by Teva/MSD & Clonmel, C-119/22, C-149/22

First MA for product A protected by basic patent → SPC for A granted

Second MA for combination A+B → second SPC for A+B required the combination to be a separate invention protected by the basic patent according to the TEVA's two-step test

Clarified in 2024: Art. 3(a) and 3(c) are autonomous requirements — a prior SPC for A does not by itself block a later SPC for A+B, provided A+B independently satisfies Art. 3(a)

ARTICLE 3(d)

The First Marketing Authorisation

ARTICLE 3(D)

Territorial Scope & Determining the First MA

Relevant territory: the European Economic Area — 27 EU Member States plus Iceland, Liechtenstein and Norway (UK marketing authorisations count only up to 31 December 2020).

Novartis / Millennium, C-207/03 & C-252/03

A Swiss MA automatically recognised in Liechtenstein can qualify as the first EEA authorisation for the purposes of calculating SPC duration. In this case, the date of the MA is the date of recognition in Liechtenstein

Seattle Genetics, C-471/14

The relevant date of the first MA is the date on which the authorisation decision is notified to its addressee — not the date of the decision itself.

How to determine the First MA

First MA	Later MA	Outcome & Reference
Veterinary use — treatment of pathology A	Human use — treatment of pathology A	✗ Destination is not a criterion — not a new “first MA”. Pharmacia, C-31/03
Human use — treatment of pathology A	Human use — treatment of pathology B	✗ Therapeutic use is not part of the product definition. Yisum, C-202/05
Veterinary use — treatment of pathology A	Human use — treatment of pathology B	✓ Formerly permissive under decision “Neurim C-130/11” — now largely superseded (see next slide).

ARTICLE 3(D)

The Restrictive Turn: Abraxis, Santen, Genmab

Abraxis, C-443/17

A marketing authorisation for a new formulation of a known active ingredient already the subject of a previous MA as an active ingredient is not the “first MA” of the product, even if the new formulation shows improve therapeutic activity.

Santen, C-673/18 (Grand Chamber), pt. 47, 53, 58

Overturms Neurim: the scope of protection of the basic patent is irrelevant to identifying the “first MA.” A new therapeutic application of a known active ingredient (or combination) does not make it a distinct “product”, if the active ingredient has already been the subject of a marketing authorisation for a different therapeutic application. A patent on a second medical use or on a new manufacturing process may still serve as the basis for an SPC, provided that the product (or combination), although already known, has never been the subject of a marketing authorisation.

Genmab, C-181/24

An earlier MA remains relevant for Art. 3(d) purposes even where it was later withdrawn — withdrawal does not erase the product’s regulatory history.

Saten did not answer the specific question relating to human/veterinary use. Pending — Case C-15/26 (reference of 12 December 2025, German Federal Patent Court, Boehringer): does an earlier human MA prevent a later veterinary MA (Aservo EquiHaler®, ciclesonide) from being the “first MA” of the product?

ARTICLE 4

Subject-Matter of Protection

Article 4 — What It Says

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 authorisation to place the corresponding medicinal product on the market, for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

Explanation

This provision draws a clear three-way distinction between the basic patent (which may have a broader scope of protection), the authorised medicinal product (the regulatory product actually placed on the market), and the SPC itself — which protects only the product covered by the marketing authorisation, within the limits of the patent, for medicinal uses authorised before expiry.

This rule prevents the certificate from being used to extend the entire patent: the SPC does not prolong the basic patent generally, only the protection of the authorised product — confirmed in *Medeva*, C-322/10, which held that the SPC concerns the product, not the medicinal product as a whole.

Example — Same Product, Different Patents, Different Scope

Type of Basic Patent	Scope of the SPC's Protection
Product patent (protects the product as such)	Covers the product itself
Process patent (protects a manufacturing process)	Covers only that process — or, where the applicable law so provides, the product directly obtained by it
New therapeutic-use patent (known or new active ingredient)	Covers not the active ingredient as such, but only the new therapeutic use

Georgetown University, C-484/12, para. 28 — citing *Neurim*, C-130/11, para. 25, and the order in *University of Queensland and CSL*, para. 39.

ARTICLE 5

Effects of the Certificate

Article 5 — What It Says

Subject to 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.

Article 5 is also the legal basis for the SPC Manufacturing Waiver: Regulation (EU) 2019/933 inserted new paragraphs — Article 5(2) to 5(5) — carving out two exceptions to these exclusive rights during the SPC term.

The SPC Manufacturing Waiver — Reg. (EU) 2019/933

SPC TERM

LAST 6 MONTHS

Export manufacturing: production during the SPC term for export to third countries where no equivalent protection exists.

Day-1 stockpiling: manufacturing in the final 6 months before expiry, for an immediate EU launch on day one after the SPC ends.

Invalidity & Challenge Mechanisms

No Centralised Opposition — Art. 19(2)

The Regulation expressly excludes any opposition procedure against a granted certificate. Unlike European patents, there is no EPO-style centralised administrative revocation — challenges are brought before national courts or, since 2023, the UPC (see below).

National Nullity Actions — Art. 15

An SPC is invalid if granted in breach of Article 3, or if the basic patent lapses prematurely, is revoked, or is limited so the product is no longer covered. Standing is broad — any person may bring a nullity action. National courts remain the exclusive forum where the basic patent is purely national, is a European patent opted out of the UPC, or is validated only in non-UPC States (e.g. Spain, Poland, Croatia).

The Unified Patent Court (UPC)

Since June 2023, an SPC based on a European patent within UPC competence (a Unitary Patent, or a classical EP not opted out) can also be annulled before the UPC — Art. 3(b) UPCA extends the Agreement to SPCs issued for a product protected by a patent. One action can invalidate the SPC across all 18 UPC States at once; for Unitary Patents, UPC competence is exclusive. Under its growing “long-arm jurisdiction” (CJEU, BSH v Electrolux, C-339/22), the UPC has also shown readiness to rule — inter partes — on validity questions reaching beyond its own Contracting States.

Most frequent grounds today: Art. 3(a) (product not sufficiently identified/necessary) and Art. 3(d) (prior marketing authorisation issues). Since Teva/MSD-Clonmel and Genmab (2024), the CJEU has substantially clarified the framework, reducing the scope for divergent national outcomes.

Guidance for Generics & Biosimilar Companies

SPC Due Diligence

1

Verify compliance with Art. 3 and the status of the basic patent (Art. 15 grounds).

Analyse the “Product”

2

Single active ingredient vs. combination vs. individual vaccine antigens.

Art. 3(a) / 3(d) Challenges

3

Today’s most fertile grounds for invalidity actions.

Bolar Exemption

4

Run bioequivalence & clinical studies; prepare the regulatory dossier during the SPC term.

Manufacturing Waiver

5

Export production, plus last-6-months “day-1” stockpiling (Reg. 2019/933).

Day-1 Launch Strategy

6

Align regulatory readiness with patent strategy to launch immediately at SPC expiry.

KEY TAKEAWAYS

Five Things to Remember

- 1 No unitary SPC** — Twenty-seven national procedures, harmonised only through CJEU interpretation — always check the local file, not just the case law.
- 2 “Product” is read narrowly** — New formulations, new therapeutic uses, and non-therapeutic carriers or adjuvants very rarely create a new “product.”
- 3 Art. 3(a) and 3(d) are today’s most fertile grounds** — Functional claims, combination products, and prior marketing histories are exactly where a validity challenge should start.
- 4 The certificate protects the product — not the whole medicinal product** — Always map the SPC's actual scope against the authorisation before assuming freedom to operate is blocked.
- 5 Plan day-one entry early** — The Bolar exemption, the manufacturing waiver, and a coordinated invalidity strategy should all converge on the same expiry date.



THANK YOU

Questions & Discussion

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