Notable updates in the realm of SPCs

Young EPLAW Congress – 28th April 2025

Núria Ribera,
Gómez-Acebo & Pombo, ES

Kristin Remvik,
Advokatfirmaet Haavind AS, NO

Wilma Kivilä,
Borenius Attorneys, FI

Delicia Clarke,
WilmerHale, UK

Chiara Perotti,
Herbert Smith Freehills, IT

POLL:

Do you have experience in advising and/or representing clients on SPC-related matters?

https://fast-poll.com/poll/00742ca7

G A _ P
Gómez-Acebo & Pombo

SPC ELIGIBILITY CRITERIA:

Overview of conditions for obtaining an SPC

G A _ P
Gómez-Acebo & Pombo

Article 2
Scope

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorization procedure (…) may, under the terms and conditions provided for in this Regulation, ***be the subject of a certificate****.*

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 authorisation*** *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.

Article 3
Conditions for obtaining a certificate

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that 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/EC or Directive 2001/82/EC, as appropriate;*

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

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

ARTICLE 3 (C) – PREVENTING DOUBLE PROTECTION

Key rulings and implications of the latest CJEU decisions (C-119/22 & C-149/22)

SPC Regulation, **Article 3 (c)**

- Article 3 (c)

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

- Article 1 (b) defines "product" as

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

- Purpose of the provision is to prevent the repetitive issuance of SPC's for the same product

Facts:
MSD v. Teva C-119/22 & MSD v. Clonmel C-149/22

- C-119/22 referred from the Finnish Market Court
  - Concerned MSD's Janumet drug for the treatment of diabetes, which combines sitagliptin and metformin.
- C-149/22 referred from the Irish Supreme Court
  - Concerned MSD's Inegy drug that acts as a cholesterol absorption inhibitor, which contains a combination of ezetimibe and simvastatin.
- In both cases, SPC holder MSD had previously obtained an SPC for a mono drug, i.e. sitagliptin alone or ezetimibe alone, and subsequently a second SPC for the above-mentioned combination drug(s), on the basis of the same basic patent(s)

- Question on article 3 (c)
  - Does article 3(c) of the SPC Regulation preclude the grant of an SPC for a product consisting of two active ingredients (A+B) where one of these active ingredients alone (A) has already been the subject of an earlier SPC and where the other active ingredient was already known in the art (B)?

Previous case law:
Actavis Group v Sanofi (C-443/12) & Actavis v Boehringer (C-577/13)

- Actavis Group v Sanofi (C-443/12): Sanofi was granted an SPC for the combination of irbesartan and hydrochlorothiazide
  - Sanofi had previously been the holder of a SPC for irbesartan alone
- Actavis v Boehringer (C-577/13): Boehringer was granted an SPC for a combination of Telmisartan and hydrochlorothiazide
  - Boehringer had previously been the holder of an SPC for telmisartan alone
- CJEU concluded that article 3 (c) precluded the grant of an SPC for the combination of A+B, where active ingredient A constitutes the "core inventive advance of that patent" or "the sole subject matter of the invention" (and A has already been the subject of an SPC alone)
  - CJEU relies on a purposive interpretation

Teva v. MSD C-119/22 & MSD v. Clonmel C-149/22

Interpretation of "product" in Article 1 (b)

- Strict definition of the term "product" according to case law
- Whether two products are identical or different depends solely on a comparison of their active ingredients, irrespective of their therapeutic applications
- If one product is a combination of active ingredients (A+B), it is distinct from a product which only contains one of the ingredients (A or B).
- The term "product" cannot have a different meaning and scope depending on whether it is interpreted in the context of Article 3 (a) or Article 3 (c)

Relevance of the basic patent in assessing article 3 (c)?

- Provisions of article 3 are cumulative and must be interpreted independently
- While article 3 (a) seeks to delimit the material scope of the SPCs by referring to the basic patent, article 3(c) seeks to limit the temporal scope of the supplementary protection conferred on a given product
- The content of the basic patent is only relevant in light of article 3 (a)

BORENIUS

ARTICLE 3(A) – DEFINING PROTECTION:

Evolution of case-law and impact of CJEU's recent decision (C-119/22 & C-149/22)

BORENIUS

Evolution of case law – Actavis I & II

- Long-standing debate over SPC protection for combination products in a situation where the patent claims a combination of compound A (novel compound) and compound B (another, already known substance)
- When is a combination product 'protected by the basic patent'?
- In *Actavis I & II,* CJEU rejected SPC protection for combination products where only one of the active ingredients of the combination was novel and constituted the **sole subject-matter of the invention**

BORENIUS

Evolution of case law – Teva UK

- The question arose again in *Teva UK* (C-121/17), where the patent disclosed new compounds (A) and included a claim for the use A together with **optionally other therapeutic ingredients** (B), which were not defined or explained in the basic patent
- Was the combination of A+B 'protected by a basic patent'?
- To determine this, the CJEU introduced a two-step test which requires that
  1) the combination of active ingredients must **necessarily fall under the invention covered by the patent**, in the light of the description and drawings of that patent, and;
  2) each of the **active ingredients must be "specifically identifiable"**, in the light of all the information disclosed by the patent, at the date of filing or priority of the application

BORENIUS

Evolution of case law – post-Teva UK

- After *Teva UK*, **unclarity still persisted over what it means to "fall under the invention"** covered by the patent
  - » Is it sufficient that the product is expressly mentioned in the claims? Or should the combination be described in the description and drawings? Should there be data? What else is required?
- These questions were at the center of the recent CJEU ruling in the joined cases C-119/22 and C-149/22, where both patents included a claim for A+B (with A being a novel compound disclosed in the basic patent, and B being an already known compound)

BORENIUS

Joined cases C-119/22 and C-149/22

- The CJEU held that **it does not suffice that a product is expressly mentioned in the claims** of the basic patent
- It is also necessary that that product **necessarily falls under the invention** covered by that patent in the light of the description and drawings
- If the mere mention would suffice, without disclosing **how that product constitutes a technical feature required for the solution** of the technical problem, this would make it possible to obtain an SPC for a product which is **not the result of the research which led to the invention protected by the same patent** (para. 64)

BORENIUS

Joined cases C-119/22 and C-149/22

- The CJEU provided some clarification as to what is required for the product to "fall under the invention covered by the patent"
  - » The specification of the patent must disclose **how the combination of those two active ingredients is a feature required for the solution of the technical problem** disclosed by the same patent, i.e. how it solves the technical problem
  - » The fact that one of the active ingredients is known at the priority date does not necessarily disqualify that product from protection if the basic patent **discloses that the combination of the two active ingredients has a combined effect going beyond the mere addition of the effects** of those two active ingredients and which contributes to the solution of the technical problem
- In the case C-149/22, it was apparent from the request for a preliminary ruling that that patent did not disclose such a combined effect

BORENIUS

Unpacking the CJEU's ruling

- The ruling makes clear that a **mere mention of the product in the claims is not sufficient**
- The patent specification must **disclose how the combination solves the technical problem** → What level of disclosure is sufficient?
  - » AG seems to imply that it must be clear form the patent that the combination represents a true innovation instead of leaning solely on the innovativeness of the new compound
  - » AG held that there should be something **beyond speculation**, such as disclosure of innovative 'synergistic effect', ability to function well together, absence of dangerous side effects
  - » CJEU refers to AG Opinion and emphasizes the need to demonstrate how the combined effect contributes to solving the technical problem but is more ambiguous in its conclusions
- Tension between the patent and SPC regimes

BORENIUS

Unpacking the CJEU's ruling

- Requirements fulfilled if the basic patent discloses a combined effect that goes beyond **the mere addition of the effects of the two active ingredients**
  - » Intended as a threshold for a combined effect? Same as 'synergistic' effect?
- CJEU has recurrently referred to the assessment being made at the filing or priority date
  - » What does it mean for taking into account post-published data?
- Possible implications
  - » Risk of deviating decisions in national authorities and courts
  - » Going forward, patent applicants will have to carefully consider how to disclose combination products in patent applications

WILMERHALE

WILMER CUTLER PICKERING HALE AND DORR LLP

ARTICLE 3(d)
and second medical use SPCs

WILMERHALE

WILMER CUTLER PICKERING HALE AND DORR LLP

Article 3(d) and second medical use SPCs

Article 3(b): "**a valid authorisation** to place the product on the market as a medicinal product has been granted…"

Article 3(d): "*the authorisation… is* ***the first authorisation to place the product on the market*** *as a medicinal product.*"

Original interpretation – if a previous MA had been granted for a product with the same active ingredient (AI), a subsequent SPC could not be obtained for a later product, even if it treats a different disorder (indication). **Intended use was irrelevant.**

Neurim **C130/11 (2012)** – **broader interpretation** applied. SPC approval could be granted for any new use of a previously approved product with the same active ingredient. **Intended use was relevant.**

Santen **C-673/18 (2020)** – *Neurim* should be abandoned. Original **narrower interpretation** should be applied – SPCs are not available for existing products for which new medical uses have been found. **Intended use was irrelevant.**

> *"Article 3(d) … must be interpreted as meaning that an MA cannot be considered to be the first MA, for the purpose of that provision, where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of an MA for a different therapeutic application."*

WILMERHALE

WILMER CUTLER PICKERING HALE AND DORR LLP

Article 3(d) and second medical use SPCs

Article 3(b): "**a valid authorisation** to place the product on the market as a medicinal product has been granted…"

Article 3(d): "*the authorisation… is* ***the first authorisation to place the product on the market*** *as a medicinal product.*"

Newron **[2024] EWCA 1471** – Applied *Santen* in the UK CA.

Merck Serono **[2025] EWCA Civ 45**

- SPC application pre-*Santen.* Two earlier MAs granted for medicinal products containing the same AI but for different indications.
- UKIPO decision handed down post-*Santen*, applying *Santen* → SPC not granted.
- Appealed to UK HC – upheld UK IPO and said *Santen* applies *ex tunc*.
- Appealed to UK CA – upheld UK IPO and UK HC. While UK courts are no longer bound by assimilated EU case law, they are bound by post-transition case law that modifies or applies EU case law in a binding UK court. As *Newron* applied *Santen*, the UK CA was bound by it. **Intended use was irrelevant. UK court maintained a narrow interpretation, consistent with the CJEU.**
- Concluded that *Santen* provided greater legal certainty and aligned with the objectives of the SPC Regulation.

NEW SPC REGULATION PROPOSAL

Influence of the case-law and future outlook

Background - current SPC Regulation

- SPCs = National rights, examined and granted nationally
- Discrepancies in substantive assessment between national offices, giving rise to lots of referrals to the CJEU (26% divergence for applications between 2004-2014)
- Procedural differences:
  - Timing of grant of SPCs differes across countries
  - Quality of assessment varies – thorough v. rubber-stamping exercise
- Increased costs and administrative burden for applicants
- Unitary Patent – but with “national SPCs”

New SPC Regulation Proposals – procedural features

- **Centralised SPC examination and opposition regime** – single examining body

EUIPO
EUROPEAN UNION
INTELLECTUAL PROPERTY OFFICE

- **Unitary SPC** – 2 new draft regulations relevant to Medicinal Products:

EUROPEAN
COMMISSION

Brussels, 27.4.2023
COM(2023) 231 final

2023/0130 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the supplementary protection certificate for medicinal products (recast)

EUROPEAN
COMMISSION

Brussels, 27.4.2023
COM(2023) 222 final

2023/0127 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

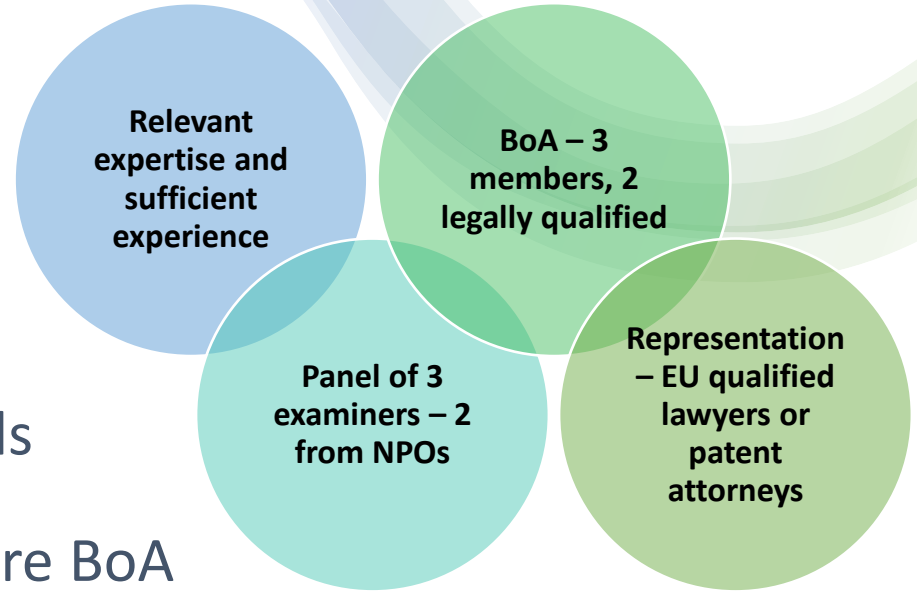
on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013

New SPC Regulation proposal – procedural features

- **Centralised Application mandatory** if applicant has EP/UP and centralised MA; not available for national patents and/or national Mas ("**closing the national route**")
- Recast SPC Regulation – EUIPO to issue **binding** final opinion resulting in **bundle of national SPCs** for EU 27
- Regulation for Unitary SPCs – **single Unitary SPC** for 18 participating states
- "**Combined**" application also available – for Unitary SPC + national SPCs for non-participating states following a single assessment

Centralised procedure at EUIPO

- New EUIPO SPC Division

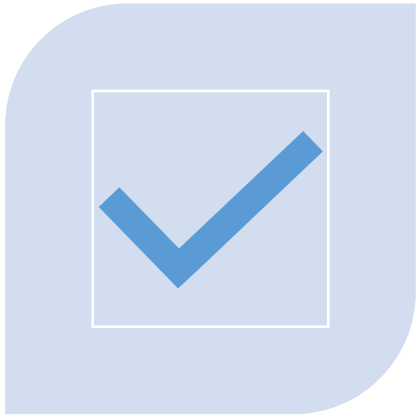


- Third party observations, oppositions, and appeals

– Applicants can also appeal negative decision before BoA

- Revocation actions against SPCs based on EP/UP remain available in parallel (national courts or UPC)

New SPC Regulation Proposal – substantive features



CHANGES TO RECITALS AND SUBSTANTIVE PROVISIONS

NEW RECITALS ASSISTING IN THE INTERPRETATION OF OPERATIVE PROVISIONS

INCORPORATION OF ESTABLISHED CJEU CASE LAW - E.G. **CASE C-121/17 (*TEVA VS GILEAD*)**

Recital (8) – Product covered by basic patent in force

- ***Teva test* -** to determine whether Art. 3(a) of the SPC Regulation is met
- A product is protected by the basic patent when it **falls under the invention** covered by the basic patent, as interpreted by the skilled person at the filing/priority date of the patent (**necessarily requirement**)
- The product is either **individualised** or meets a **general functional definition** used by one of the claim of the basis patent (**specifically identifiable requirement**)

Recital (8) – Product covered by basic patent in force

8) One of the conditions for the grant of a certificate should be that the product is protected by the basic patent, in the sense that the product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art ~~by~~***in light of*** the description ***and drawings*** of the patent***, on the basis of that person's general knowledge in the relevant field and of the prior art at the*** ~~on its~~ filing date ***or priority date of the basic patent***. This should not necessarily require that the active ingredient of the product be explicitly identified in the claims~~.~~ or, in the event of a combination product, this should not necessarily require that each of its active ingredients be explicitly identified in the claims, provided that each ~~of them~~***active ingredient*** is specifically identifiable in the light of all the information disclosed by that patent***, on the basis of the prior art at the filing date or priority date of the basic patent***. **[Am. 3]**

Art. 3(3) – Economically linked entities

- **Biogen and AHP manufacturing cases -** to determine whether Art. 3(c) of the SPC Regulation is met
- **"One SPC per applicant rule" –** if a product is protected by a number of basic patents in force, each patent holder may obtain a SPC provided that they are **different** holders of basic patents
- Applied on the basis of **Art. 3(c) and Recital 17 of the Regulation (EC) No 1610/96 for SPCs for plant protection products**
- No elaboration on conditions for patent holders to be **different**

Art. 3(3) – Economically linked entities

3. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for that product may be issued to each of those holders, where they are not economically linked. ***The same principle shall apply mutatis mutandis to applications submitted by the holder concerning the same product for which one or more certificates or unitary certificates have been previously granted to other different holders of different patents.*** **[Am. 17]**

(12a) 'economically linked' means, in respect of different holders of two or more basic patents protecting the same product, that one holder, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with another holder. **[Am. 15]**

New SPC Regulation – Main goals

What's next?

- European Commission proposal presented before EU Parliament in Feb 2024 and approved with amendments
- Now awaiting Council's 1st reading position, then interinstitutional negotiations will open up
- May be adopted in the course of 2025 (but most likely during 2026)

Thank you!

Any questions?

Kristin Remvik (Advokatfirmaet Haavind AS, NO)
Wilma Kivilä (Borenius Attorneys, FI)
Delicia Clarke (WilmerHale, UK)
Chiara Perotti (Herbert Smith Freehills, IT)
Núria Ribera (Gómez-Acebo & Pombo, ES)

GA_P Gómez-Acebo & Pombo

Haavind

BORENIUS

WILMERHALE

WILMER CUTLER PICKERING HALE AND DORR LLP

HERBERT SMITH FREEHILLS