Supplementary protection certificates – where are we heading?

5 April 2022

Ulla Klinge - *uk@inspicos.com*
PhD (Law), European Patent Attorney

Agenda

1. Products eligible for SPC protection
2. Basic requirements (Art. 3):
    - (a) protected by a basic patent in force
    - (b) valid marketing authorisation for the product
    - (c) product not already subject of a certificate
    - (d) authorisation in (b) is the first marketing authorisation for the product
3. Third party SPC
4. Manufacturing waiver
5. Recent initiative from the EU Commission re unitary SPC

Products eligible for SPC protection

- Strict interpretation
- Pharmacological/immunological/metabolic action of their own required
- Case law inconsistent – excipient/adjuvant/carrier NO – safener YES
- Distinction between ”active ingredient” and ”adjuvant” unclear

Protected by a basic patent in force, Art. 3(a)

Not an infringement test

Rather (qualified) scope of protection test

- ”specified”; (*Medeva*); ”relate implicitly but necessarily and specifically” (*Eli Lilly*);
- ”necessarily fall under the invention” and be ”specifically identifiable” (*Teva)*

- ”necessarily come within the scope of the invention” and
- ”infer directly and unambiguously” that the product comes within the scope of the invention
- Product based on ”independent inventive step” not SPC eligible (*Royalty Pharma*)

Protected by a basic patent in force, Art. 3(a) – **Case C-121/17***, *Teva*

TRUVADA® – tenofovir disproxil (fumarate) **(TDF)** and emtricitabine **(FTC)**

- Claim 25: **tenofovir disproxil (TD)**
- Claim 27: ”A pharmaceutical composition comprising a compound acccording to any one of claims 1-25 together with a pharmaceutically acceptable carrier and **optionally other therapeutic ingredients**

- SPC: Composition containing **tenofovir disproxil** together with emtricitabine

- *Decided by the Grand Chamber of the CJEU

Protected by a basic patent in force, Art. 3(a), **Case C-121/17**, *Teva* (contd.)

Two-part test:

- - the product **must necessarily**, in the light of the description and drawings of that patent, **fall under the invention** covered by that patent

- -the product **must be specifically identifiable**, in the light of all the information disclosed by that patent

Protected by a basic patent in force, Art. 3(a), **Case C-650/17**, *Royalty Pharma*

Basic patent to a method for lowering blood glucose levels by administration of DP IV inhibitor

SPC: sitagliptin

Sitagliptin was developed after the filing date of the basic patent, specifically patented and subject of SPC protection

Protected by a basic patent in force, Art. 3(a), **Case C-650/17**, *Royalty Pharma* (contd.)

Two-part test:

- ”it **corresponds to a general functional definition**... and **necessarily comes within the scope of the invention covered by that patent**... provided that it is **specifically identifiable**, in the light of all the information disclosed”

- A person skilled in the art is able to ”***infer directly and unambiguously***”

Protected by a basic patent in force, Art. 3(a), Case C-650/17, *Royalty Pharma* (contd.)

- A product is not protected by a basic patent in force, if ”**it was developed after the filing date** of the application for the basic patent, following an **independent inventive step**

A valid authorisation to place the product on the market, Art. 3(b)

Decision	Patent	MA	SPC	Main conclusion
C-322/10, Medeva	A + B	A + B + C + D	A + B	"specified in the wording of the claims"
C-518/10, Yeda	A + B	A	No SPC	"is not the subject of any claim relating to that active ingredient alone"
C-6/11, Daiichi	A	A A + B	A No SPC for A + B	"identified in the wording of the claims"

: A = Irbesartan; B = hydrochlorothiazide
Actavis II: A = telmisartan; B = hydrochlorothiazide

The product is not already subject to a certificate, Art 3(c)

	Basic patent	1.MA	1.SPC	2.MA	2.SPC	Ruling
Actavis I	A A + diuretic	A	A	A + B	A + B No	A "core inventive advance" B not protected as such by the patent Combination not totally separate innovation
Actavis II	A A + B[a]	A	A	A + B	A + B No	A "sole subject-matter of the invention" B not subject-matter of the invention

The MA is the first MA for the product,, **Case C-130/11**, *Neurim*

Circadin - melatonin for use in the treatment of insomnia

Prior known uses of melatonin for regulating breeding activity of sheep

CJEU: "...**the mere existence of an earlier [MA] obtained for a veterinary medicinal product** does not preclude the grant of an SPC **for a different application of the same product**...**provided that the application is within the limits of the protection conferred by the basic patent** ..."

The MA is the first MA for the product, **Case C-443/17**, *Abraxis*

Paclitaxel formulated as albumin-bound nanoparticles, ”nab-paclitaxel” for use in the treatment of certain cancers

Prior formulations of paclitaxel for the treatment of certain cancers

CJEU: ”the marketing authorisation… relied on in support of an application for a[n SPC] **concerning a new formulation of an old active ingredient**, **cannot be regarded as being the first [MA] for the product**…in the case where that active ingredient has already been the subject of a marketing authorisation as an active ingredient”

The MA is the first MA for the product, **Case C-673/18***, *Santen*

Ciclosporin (as eye drops in emulsion) for use for the treatment of severe keratitis

Prior known uses of ciclosporin (as oral solution) in the prevention of transplant rejection and in the treatment of endogeneous uveitis (inflammation of uvea -the middle part of the eye)

*Decided by the Grand Chamber of the CJEU

The MA is the first MA for the product, **Case C-673/18**, *Santen* (contd.)

"It follows that, **contrary to what the Court held in…*Neurim***, to define the concept of 'first [MA for the product] as a medicinal product' for the purpose of Article 3(d) of Regulation No 469/2009, **there is no need to take into account the limits of the protection of the basic patent**."

"That interpretation also enables **a fair balance to be struck** between, on the one hand, the objective of the SPC regime…of **compensating for the inadequacy of protection** conferred by a patent for the purpose of covering the investment put into research concerning new active ingredients or combinations of active ingredients and, therefore, of encouraging such research and, on the other hand, …. to achieve that objective in a manner that **takes into account all the interests at stake, including those of public health**…."

The marketing authorisation is the first MA for the product, Art. 3(d) – summary

Neurim – applying a teleological interpretation: aim of SPC regulation not only to encourage research into new products but also a new application of a new or known product – aim of SPC regulation to compensate for insufficient patent life

Abraxis and *Santen* – aim of SPC regulation to protect research leading to first marketing of a product

Third-party SPC

- An SPC may – presumably – be based on a third party marketing authorisation – Biogen case (C-181/95)

- Attempts to refer questions to CJEU sofar unsuccessful

Reap What You Sow! — But What About SPC Squatting? by Jens Schovsbo, Timo Minssen, Ulla Callesen Klinge :: SSRN

Manufacturing waiver

- Permits a third party to manufacture a medicinal product protected by an SPC for the exclusive purpose of export to countries outside the EU
- For the final six months prior to SPC expiry, the right to manufacture extends to manufacture for stockpiling in the country of manufacture for release on to the market in the EU upon SPC expiry
- Obligation to notify SPC holder and national patent office
- Introduced 1 July 2019

Recent initiative from the EU Commission – unitary SPC?

- Unitary SPC on the basis of European patent with unitary effect? and/or

- Unified procedure for granting bundles of national SPCs (virtual authority?)

Thank you for your attention!