Velkommen

SPC – status april 2024

18. april 2024

inspicos

EUROPEAN PATENT ATTORNEYS

Agenda

- **Status of the SPC reform**
  - Unitary SPC's (USPC)
  - Amendments to existing SPC regulations
- **Pending referrals to the CJEU**
- **Is *Santen* still good law?**

Status of the SPC reform

- **4 Regulations**
  - Existing SPC regulation for medicinal products (recast)
  - Unitary SPC for medicinal products
  - Existing SPC regulation for plant protection products (recast)
  - Unitary SPC for medicinal plant protection products

Status of the SPC reform

- 27 April 2023: First draft of regulations
- 13 October 2023: revised drafts after hearing
- 28 February 2024: Revised proposals approved by the European Parliament
- Awaiting consideration by the Commission and the Council

Status of the SPC reform

- **SPC regulation for medicinal products (recast)**
- **Main characteristics**
  - Introduction of centralised examination
  - Introduction of pre-grant opposition procedure
  - Revised wording of Article 3
  - Revised wording of Article 6
  - References to CJEU case law in recitals

Status of the SPC reform

- Centralised filing and examination of SPC applications by the EUIPO
- Mandatory in relation to unitary SPC's
- Mandatory in relation to SPC's based on non-unitary patents and a centralised marketing authorisation for medicinal products (EMA authorisation)
- Binding opinion
- Opposition procedure during two months after publication of positive examination opinion
- SPC to be granted by national patent authorities for non-unitary SPC's
- SPC to be granted by EUIPO for unitary SPC's

Status of the SPC reform, Art. 3 (recast)

Conditions for obtaining a certificate

1. 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, all of the following conditions are fulfilled:

- (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 ../..[2023/0132(COD), Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, 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.

Status of the SPC reform, Art. 3 contd.

2. By way of derogation from paragraph 1, a certificate shall not be granted under this Chapter, in a Member State, on the basis of a national application where the requirements of Article 20(1) are fulfilled for the filing of a centralised application in which that Member State would be designated.

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.

NB: Art. 2 (1) (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"

Status of the SPC reform, Art. 6 recast

Entitlement to the certificate

1. The certificate shall be granted to the holder of the basic patent or ~~his~~ to the successor in title of that holder.

2. Notwithstanding paragraph 1, where a basic patent has been granted in respect of a product that is the subject of an authorisation held by a third party, a certificate for that product shall not be granted to the holder of the basic patent without the consent of that third party.

Status of the SPC reform, Art. 8 recast

Content of the application for a certificate

- The application for a certificate shall contain the following:
- (a) the name and address of the applicant;
- …
- …
- (da) if applicable, the consent of the third party referred to in Art. 6(2) of this Regulation

Status of the SPC reform – new recitals

(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 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 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 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 .

Status of the SPC reform – new recitals

(9) To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary, may protect the same product in a Member State. Therefore it should be required that the product, or any derivative such as salts, esters, ethers, isomers, mixtures of isomers, complexes or biosimilars, should not have already been the subject of a prior certificate, whether for the same therapeutic indication or for a different one.

Status of the SPC reform – new recitals

(11) To ensure balanced protection, however, a certificate should entitle its holder to prevent a third party from manufacturing not only the product identified in the certificate but also therapeutically equivalent derivatives of that product, such as salts, esters, ethers, isomers, mixtures of isomers or complexes, as well as biosimilars, even where such derivatives are not explicitly mentioned in the product description on the certificate. There is therefore a need to consider that the protection conferred by the certificate extends to such equivalent derivatives, within the limits of the protection conferred by the basic patent.

Status of the SPC reform – new recitals

(13) Where the marketing authorisation submitted in support of the application for a certificate for a biological medicinal product identifies that product by means of its International Nonproprietary Name (INN), the protection conferred by the certificate should extend to all biosimilar having the same International Nonproprietary Name as the product referred to in the marketing authorisation, irrespective of possible minor differences between a subsequent biosimilar and the product authorised, which are usually unavoidable given the nature of biological products.

Pending referrals before the CJEU

SPC's for combination products

- Case C-119/22 – Referral by the Finnish Market Court – Teva vs. MSD

- C-149/22 – Referral by the Irish Court of Appeal -MSD vs. Clonmel Healthcare Limited

Case C-119/22 – Referral by the Finnish Market Court – Teva vs. MSD

- 1st SPC on 13 March 2012 for the product Januvia (sitagliptin as monotherapy).
- 2nd SPC on 20 March 2012 for the product Janumet (sitagliptin and metformin)
- Same basic patent - EP 1 412 357

Case C-119/22 – Referral by the Finnish Market Court – Teva vs. MSD

- Basic patent: EP 1 412 357
- Claim 1: Compound of the formula I (Markush formula)
- Claim 15: Compound selected among 33 specific compounds (sitagliptin no. 7 thereof)
- Claim 25: Pharmaceutical composition comprising a compound acc. to any one of claims 1-15 and one or more compounds selected from a group (comprising 14 different types of compounds, including biguanides, of which two – metformin and phenformin – were known at the priority date)
- Claim 28: Compound which is sitagliptin
- Claim 30: A pharmaceutical composition as claimed in claim 25 comprising a compound of any one of claims 1 to 15 or a pharmaceutically acceptable salt thereof, metformin and a pharmaceutically acceptable carrier.

Case C-119/22 – Referral by the Finnish Market Court – Teva vs. MSD

- Teva requested invalidity of the combination SPC as being granted in breach of
- Art. 3(a) – combo not protected by basic patent
- Art. 3(c) – monotherapy SPC already granted
- Art. 3(d) – combo MA not first MA to place combo on the market

Case C-119/22 – Referral by the Finnish Market Court – Teva vs. MSD

- C-443/12 (Actavis I):
- "…for the purpose of the application of Article 3(c) …it cannot be accepted that…may obtain a new SPC… a medicinal product containing, on the one hand, the principle active ingredient, protected as such by the holder's basic patent and constituting…the core inventive advance of that patent, and, on the other, another active ingredient which is not protected as such by that patent."
- **C-577/13 (Actavis II): "**Article 3(a) and (c) must be interpreted as meaning that, where a basic patent includes a claim to a product comprising an active ingredient which constitutes the sole subject-matter of the invention, for which the holder of that patent has already obtained a supplementary protection certificate, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, that provision precludes the holder from obtaining a second supplementary protection certificate for that combination."

Case C-119/22 – Referral by the Finnish Market Court – Teva vs. MSD

C-121/17 (Teva): ”Article 3(a) …must be interpreted as meaning that a product…is “protected by a basic patent in force”...where those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

– the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

– each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.”

Case C-119/22 – Referral by the Finnish Market Court – Teva vs. MSD

C-650/17 (Royalty Pharma): "Article 3(a)…must be interpreted..that a product is protected by a basic patent in force.. if it ……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 by that patent, by a person skilled in the art, based on that person's general knowledge in the relevant field at the filing date or priority date of the basic patent and on the prior art at that date."

"In so doing, the Court [ref. to Teva – C121/17] clearly relied on an interpretation of Article 3(a) of Regulation No 469/2009, in the context of which the concept of 'core inventive advance' is not relevant."

Case C-119/22 – Referral by the Finnish Market Court – Teva vs. MSD

- Legal issue:
- apparently different interpretation of the term ”product” in relation to Art. 3(a) and Art. 3 (c), respectively

Case C-119/22 – Referral by the Finnish Market Court – questions referred

1. What criteria must be applied to determine when a product has not already been granted a supplementary protection certificate within the meaning of Article 3(c) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products ('SPC Regulation')?

2. Must the assessment of the condition set out in Article 3(c) of the SPC Regulation be regarded as being different from the assessment of the condition set out in Article 3(a) of that regulation, and if so, in what way?

Case C-119/22 – Referral by the Finnish Market Court – questions referred

3. Must the statements on the interpretation of Article 3(a) of the SPC Regulation in the judgments of the Court in Case C-121/17 and Case C-650/17 be regarded as relevant to the assessment of the condition in Article 3(c) of the SPC Regulation and, if so, in what way? In that connection, particular attention should be paid to the statements made in those judgments regarding Article 3(a) of the SPC Regulation, specifically:

- the essential meaning of patent claims; and
- the assessment of the case from the point of view of a person skilled in the art and in the light of the prior art at the filing date or priority date of the basic patent.

Case C-119/22 – Referral by the Finnish Market Court – questions referred

4. Are the concepts 'core inventive advance', 'central inventive step' and/or 'subject matter of the invention' of the basic patent relevant to the interpretation of Article 3© of the SPC Regulation and, if any or all of those concepts are relevant, how are they to be understood for purposes of interpreting Article 3(c) of the SPC Regulation? For the purposes of applying those concepts, does it make any difference whether the product in question consists of a single active ingredient ('mono-product') or a combination of active ingredients ('combination product') and, if so, in what way? How is the latter question to be assessed in a case in which the basic patent contains, on the one hand, a patent claim for a mono-product and, on the other hand, a patent claim for a combination product, the latter patent claim relating to a combination of active ingredients consisting of the active ingredient of the mono-product plus one or more active ingredients from the known prior art?

Case C-119/22 – Referral by the Finnish Market Court - status

- **Dates**
- **Date of the lodging of the application initiating proceedings**
- 17/02/2022
- **Date of the Opinion**
- 25/04/2024
- **Date of the hearing**
- 08/03/2023
- **Date of delivery**
- *Information not available*

C-149/22 – Referral by the Irish Supreme Court – MSD vs Clonmel Healthcare Limited

- 1st SPC for ezetimibe monotherapy for the treatment of high cholesterol (Ezetrol)
- 2nd SPC for combination of ezetimibe +simvastatin for the treatment of high cholesterol (Inegy)

C-149/22 – Referral by the Irish Supreme Court - MSD vs Clonmel Healthcare Limited

- Basic patent: EP 0 720 599
- Claim 1: Compound of the formula I (Markush formula)
- Claim 8: A compound which is ezetimibe.
- Claim 9: A pharmaceutical composition for the treatment or prevention of atherosclerosis…comprising a compound acc. to any one of claims 1-8, alone or in combination with a cholesterol biosynthesis inhibitor…
- Claim 16: A pharmaceutical composition of any of claims 9, 12 or 15 wherein the cholesterol biosynthesis inhibitor is selected from the group consisting of HMG CoA reductase inhibitors, squalene synthesis inhibitors and squalene epoxidase inhibitors.
- Claim 17: A pharmaceutical composition of claim 16 wherein the cholesterol biosynthesis inhibitor is selected from the group consisting of lovastatin, pravastatin, fluvastatin, simvastatin, CI-981 , DMP-565, L-659,699, squalestatin 1 and NB598.

C-149/22 – Referral by the Irish Supreme Court - MSD vs Clonmel Healthcare Limited

- Clonmel requested invalidity of the combination SPC as being granted in breach of
- Art. 3(a) – combo not protected by basic patent
- Art. 3(c) – monotherapy SPC already granted
- Art. 3(d) – combo MA not first MA to place combo on the market

C-149/22 – Referral by the Irish Supreme Court - MSD vs Clonmel Healthcare Limited – questions referred

1. (a) For the purpose of the grant of a supplementary protection certificate, and for the validity of that SPC in law, under Article 3(a) of Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, does it suffice that the product for which the SPC is granted is expressly identified in the patent claims, and covered by it; or is it necessary for the grant of an SPC that the patent holder, who has been granted a marketing authorisation, also demonstrate novelty or inventiveness or that the product falls within a narrower concept described as the invention covered by the patent?

1. (b) If the latter, the invention covered by the patent, what must be established by the patent holder and marketing authorisation holder to obtain a valid SPC ?

C-149/22 – Referral by the Irish Supreme Court - MSD vs Clonmel Healthcare Limited – questions referred

2. Where, as in this case, the patent is for a particular drug, ezetimibe, and the claims in the patent teach that the application in human medicine may be for the use of that drug alone or in combination with another drug, here, simvastatin, a drug in the public domain, can an SPC be granted under Article 3(a) of the Regulation only for a product comprising ezetimibe, a monotherapy, or can an SPC also be granted for any or all of the combination products identified in the claims in the patent?

3. Where a monotherapy, drug A, in this case ezetimibe, is granted an SPC, or any combination therapy is first granted an SPC for drugs A and B as a combination therapy, which are part of the claims in the patent, though only drug A is itself novel and thus patented, with other drugs being already known or in the public domain; is the grant of an SPC limited to the first marketing of either that monotherapy of drug A or that first combination therapy granted an SPC, A+B, so that, following that first grant, there cannot be a second or third grant of an SPC for the monotherapy or any combination therapy apart from that first combination granted an SPC?

C-149/22 – Referral by the Irish Supreme Court - MSD vs Clonmel Healthcare Limited – questions referred

4. If the claims of a patent cover both a single novel molecule and a combination of that molecule with an existing and known drug, perhaps in the public domain, or several such claims for a combination, does Article 3(c) of the Regulation limit the grant of an SPC;

(a) only to the single molecule if marketed as a product;

(b) the first marketing of a product covered by the patent whether this is the monotherapy of the drug covered by the basic patent in force or the first combination therapy, or

(c) either (a) or (b) at the election of the patentee irrespective of the date of market authorisation?

- And if any of the above, why?

Is *Santen* still good law?

- Irish Court of Appeal decision leading to C-149/22
- UK High Court decision regarding Merck's SPC for new medical use of cladribine (treatment of multiple sclerosis)
- Earlier MA for cladribine for the treatment of specific form of leukaemia
- Merck has obtained permission to appeal – appeal may be heard by Arnold LJ
- Arnold LJ in Neurim referral: "*In short, if Neurim are wrong, then the Regulation will not have achieved its key objects for large areas of pharmaceutical research: it will not be fit for purpose*"

Mange tak for opmærksomheden!

Ulla Klinge, PhD(jur), EPA

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