

CARPMAELS & RANSFORD

SPCs – where are we now?

Competition Law Association

16 July 2021

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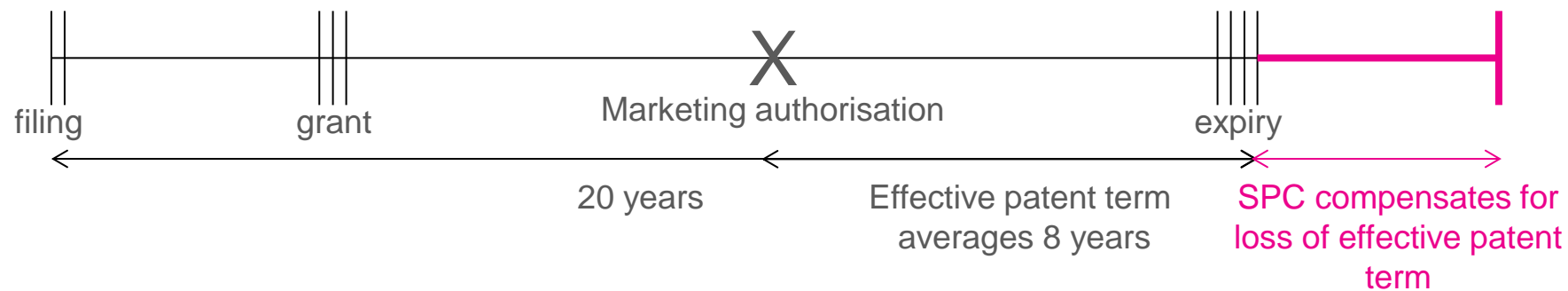
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Introduction to SPCs

- At the interface of regulatory law and intellectual property law
- Medicinal products: Regulation (EC) No 469/2009 of 6 May 2009
 - As amended by Regulation (EU) 2019/933 of 20 May 2019
- Plant protection products: Regulation (EC) No 1610/96 of 23 July 1996
- No soft law
- 41 preliminary rulings from the CJEU, national case law, and travaux
- Competition law considerations can arise

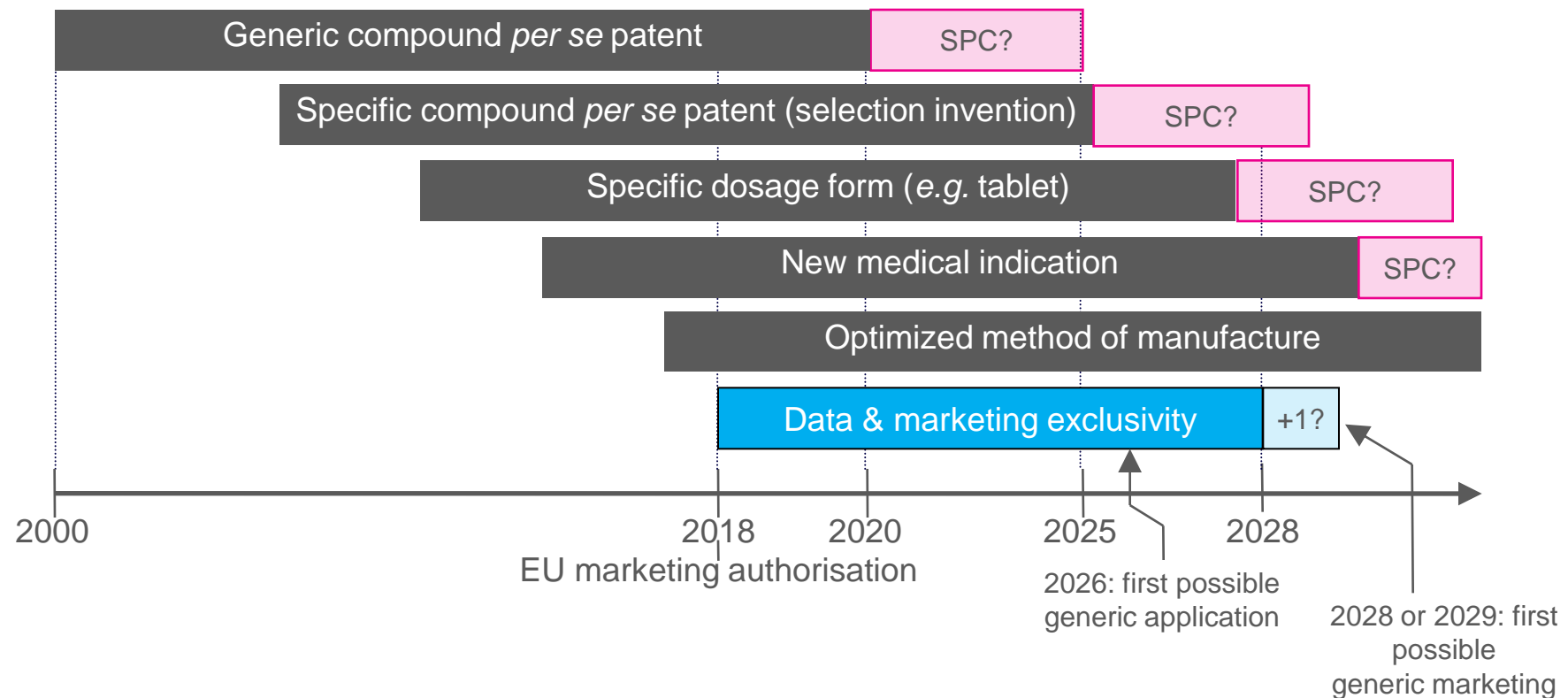
Introduction to SPCs

- In order to obtain an SPC:
 - A medical/plant protection product with marketing authorisation
 - A patent covering that product
- SPCs compensate companies for the loss of effective patent term caused by waiting for marketing authorisation



Introduction to SPCs

- SPCs can add another tier of protection for pharmaceutical products



Applying for & entitlement to the certificate

- No centralised EU procedure – SPCs are filed nationally in each country
- SPC is granted to the holder of the basic patent/successor in title
- Patent holder \neq marketing authorisation holder
 - Case C-181/95 *Biogen*

Article 1 – Definitions

- a) **medicinal product** means
 - any **substance** or **combination of substances** presented for
 - treating or preventing disease; making a medical diagnosis; or restoring, correcting or modifying physiological functions
 - in humans or animals
- b) **product** means
 - the **active ingredient** or
 - **combination of active ingredients** of a medicinal product
- c) **basic patent** means a patent which protects
 - **product as such**
 - **process to obtain a product**
 - **application of the product**

Article 3 – Conditions for obtaining an SPC

- 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 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 b) is the **first authorisation** to place the **product** on the market as a medicinal product.

Recent cases

- There have been many references to the CJEU on the interpretation of Article 3(a)
 - *C-650/17 Royalty Pharma Collection Trust* (& *C-114/18 Sandoz*)
 - *C-121/17 Teva UK and Others*
 - *C-577/13 Actavis v Boehringer*
 - *C-493/12 Eli Lilly*
 - *C-484/12 Georgetown University*
 - *C-443/12 Actavis v Sanofi*
 - *C-630/10 University of Queensland*
 - *C-518/10 Yeda Research and Development*
 - *C-6/11 Daiichi Sankyo Company*
 - *C-422/10 Georgetown University*
 - *C-322/10 Medeva*
 - *C-392/97 Farmitalia*

C-650/17 Royalty Pharma: Article 3(a)

- Royalty Pharma's basic patent (EP1084705, filed 24.04.1997):
 1. Activity-lowering effector of dipeptidylpeptidase IV (DP IV)-enzymatic activity for use in lowering the blood glucose level below the glucose concentration in the serum of a mammalian organism characteristic of hyperglycemia for alleviation of diabetes mellitus, wherein said effector results in the reduced degradation of the endogenous insulinotropic peptides GIP1-42 and GLP-17-36 by DP IV.
 2. Activity-lowering effector for use according to claim 1, wherein said effector is a **DP IV-inhibitor**.
- Sitagliptin belongs to the group of **DP IV inhibitors**, but it is not further specified in the patent
- Sitagliptin was developed by licensee MSD **after** the filing date of the basic patent

C-650/17 Royalty Pharma – CJEU judgment

Answer to the first and second questions

- 43 *It follows from the foregoing that the answer to the first and second questions is that Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that a **product is protected** by a basic patent in force, within the meaning of that provision, if it **corresponds to a general functional definition used by one of the claims of the basic patent and necessarily comes within the scope of the invention** covered by that patent, but is not otherwise indicated in individualised form as a specific embodiment of the method of 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.***

C-650/17 Royalty Pharma – CJEU judgment

Answer to the first and second questions

- Product does not need to be expressly mentioned in the claims or defined structurally
- A functional definition is okay, **if**
 - the skilled person can still specifically identify the product in the claims in light of
 - the information in the patent,
 - the general knowledge, and
 - the prior art
 - at the effective filing date of the patent

C-650/17 Royalty Pharma – CJEU judgment

Answer to the third question

- 50 *In the light of the foregoing, the answer to the third question is that Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that a product is **not protected** by a basic patent in force, within the meaning of that provision, if, although it is covered by the functional definition given in the claims of that patent, **it was developed after the filing date** of the application for the basic patent, **following an independent inventive step**.*
- A product which was developed after the filing date or priority date of the basic patent, following an independent inventive step, **cannot** be “specifically identifiable” ([48] and [49])
- Subsequent recent national litigation
 - Royalty Pharma, sitagliptin, Germany: BPatG 14 W (Pat) 12/17 [2020]
 - Ono Pharmaceuticals, nivolumab/pembrolizumab, France: case nos. 18/10540 and 18/10522
 - Wyeth, osimertinib, France: case no. 19/19410

C-673/18 *Santen*: Article 3(d)

– C-130/11 *Neurim*:

- “27 In the light of all the above considerations, the answer to the first and third questions is that Articles 3 and 4 of the SPC Regulation are to be interpreted as meaning that, in a case such as that in the main proceedings, 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** for which an MA has been granted, **provided that the application is within the limits of the protection conferred by the basic patent relied upon** for the purposes of the application for the SPC.”

– C-673/18 *Santen*:

- “53 It follows that, **contrary to what the Court held in paragraph 27 of the judgment 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.**”

C-673/18 *Santen*

- “On those grounds, the Court (Grand Chamber) hereby rules:
- Article 3(d) 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 must be interpreted as meaning that **a marketing authorisation cannot be considered to be the first marketing authorisation**, 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 a marketing authorisation for a different therapeutic application.**”

Open issues?

- Article 1(b)?
 - What is the active ingredient of a medicinal product?
- Article 3(a)?
 - Is there clarity?
- Article 3(b)?
 - MA holder \neq patentee?
- Article 3(c)?
 - Ownership of the basic patent?

Interface with competition law

- “abusive nature of the lack of transparency which AZ displayed when filing the SPC applications”
 - Case T-321/05 Astra Zeneca v Commission, 1 July 2010
 - Appeal dismissed: Case C-457/10 P, 6 December 2012

- “complex legal strategy”
 - Decision no. 693/214 of the Consiglio di Stato (Pfizer’s Xalatan®)

Where are we going after Brexit?

- SPC Regulation adapted for the UK
- Different types of authorisation now available within the UK
- Questions over Northern Ireland
- Parallel imports & exhaustion
- Unitary SPC

Thank you

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