

# Fordham IP Conference 2014

SPCs – One step forward and two steps back, or  
“in essence” what on earth is going on?

*Friday 25<sup>th</sup> April 2014*

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# Agenda

## Supplementary Protection Certificates

1. Introduction/Reminder of the basics (Brian)
2. The Human Genome Sciences/  
Eli Lilly Reference (Brian)
3. Actavis v Sanofi; Georgetown II (Rian)
4. What does the future hold? (Rian)

# Introduction

## What is an SPC?

- A Supplementary Protection Certificate is a *sui generis* IP right that commences at the expiry of a basic patent
- It lasts for up to 5½ years
- SPCs were created by, and are governed by, an EU Regulation (469/2009 replacing 1768/92)
- SPCs sit on the boundary of patent law and regulatory law
- SPCs are very important. Up to 80% of the total revenue for a major pharmaceutical product can be generated in the SPC term

# SPCs – Basic Concepts and Definitions

## Three key definitions:

**Basic patent:** a patent protecting: (i) a product as such; (ii) a process or (iii) an application for a product

**Product:** the active ingredient or combination of active ingredients of a medicinal product

**Medicinal Product:** the substance presented for treating or preventing disease in humans



# How can an SPC be granted?

## Article 3 – Conditions for obtaining a Certificate

A certificate shall be granted if:

- (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.***” (Emphasis added)

# Subject Matter and Effects of SPCs

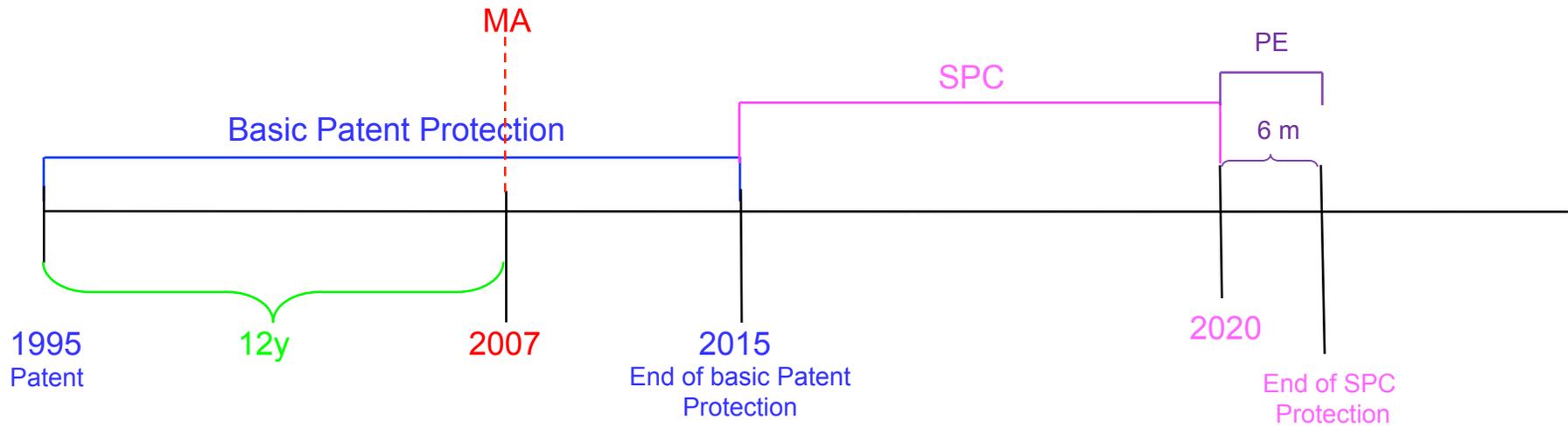
## Article 4: Subject Matter of Protection

- *“Within the limits of the protection conferred by the basic patent, the protection conferred... 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 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 the basic patent and shall be subject to the same limitations and same obligations”*

# How to calculate the SPC duration



- Supplementary Protection Certificate (SPC)
- Basic Patent Protection
- Paediatric Extension

SPC :  $12 - 5 = 7$  but 5 max plus six months extension

# The State of Play at the end of 2012

## Article 3

Sub-Section	CJEU Interpretation	Outstanding Issues
a) The product is protected by a basic patent	The product must be “specified/ identified in the wording of the claims” ( <u>Medeva</u> )	<ul style="list-style-type: none"> <li>• What does “specified” mean?</li> <li>• Markush formulae?</li> <li>• What about classes of product – e.g. diuretics?</li> <li>• Functional definition e.g. “A binds to B”?</li> </ul>
b) Valid authorisation... has been granted	Any MA containing the product will suffice (e.g. an MA for A+B is an authorisation for A) ( <u>Georgetown</u> )	<ul style="list-style-type: none"> <li>• How does this approach fit with the definition of “product”?</li> <li>• Did the MA have to be granted to the patentee?</li> <li>• Did the MA holder need to consent to the SPC application?</li> </ul>
c) The product has not already been the subject of a certificate	There can be more than one SPC for any given product (Article 3(2) Plant Protection Regulation and <u>Biogen/AHP</u> ); One SPC per patent? ( <u>Medeva</u> )	<ul style="list-style-type: none"> <li>• Did the CJEU mean to disturb the orthodoxy of one SPC <u>per product</u> per patent?</li> </ul>
d) The authorisation in (b) is the first authorisation to place the product on the market	Any earlier MAs can be ignored if the earlier medicinal product falls outside the scope of the later basic patent ( <u>Neurim</u> )	<ul style="list-style-type: none"> <li>• Encourages innovation by second medical use even if the interpretation is somewhat teleological</li> </ul>

## The State of Play at the end of 2012 (cont.)

- Article 1: “Product” – restrictively interpreted as active ingredient/combination only; excipients were excluded (MIT)
- Article 4/5: Broadly interpreted: An SPC for A would, like a patent, be infringed by any medicine containing A regardless of the presence of other active ingredients (Novartis – Valsartan)
- Article 13: “First authorisation to place the product on the market in the Community” interpreted very literally (Novartis – Liechtenstein)

## Most important decisions in 2013

- Eli Lilly v HGS: Article 3(a); 3(b)  
(C-493/12 – decision of 12<sup>th</sup> December 2013)
- Georgetown II: Article 3(c)  
(C-483/12 – decision of 12<sup>th</sup> December 2013)
- Actavis v Sanofi: Article 3(c)(3(a))  
(C-443/12 – decision of 12<sup>th</sup> December 2013)

### **OTHER DECISIONS**

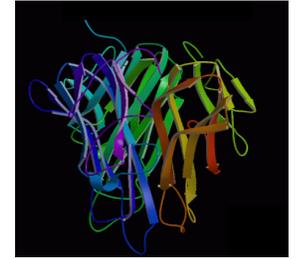
- Glaxosmithkline Biologicals v Comptroller – definition of product  
(C210/13 – Reasoned Order of 14<sup>th</sup> November 2013)
- AstraZeneca v Comptroller – duration of an SPC/what counts as the first MA?  
(C617/12 – Reasoned Order of 14<sup>th</sup> November 2013)

Eli Lilly v Human Genome Sciences

Articles 3(a) and 3(b)

*12 December 2013*

# Eli Lilly v HGS – The Facts and the Reference



- HGS' patent claimed the nucleotide and amino acid sequence for neutrokinine-alpha. It was filed before any traditional “wet” experimental work had been performed to determine neutrokinine-alpha's functions.
- Lilly applied for a declaration that if HGS sought an **SPC based upon Lilly's MA** for Tabalumab, an antibody proposed for use in autoimmune diseases, the SPC would be invalid.
- In light of the *Actavis v Sanofi* reference, Warren J. referred question of whether it was sufficient that the antibody or antibodies were defined in terms of their **binding characteristics to a target protein**, or was it necessary to provide a **structural definition** for the antibody or antibodies?

HGS' patent  
+  
Eli Lilly's MA  
= HGS'  
SPC??

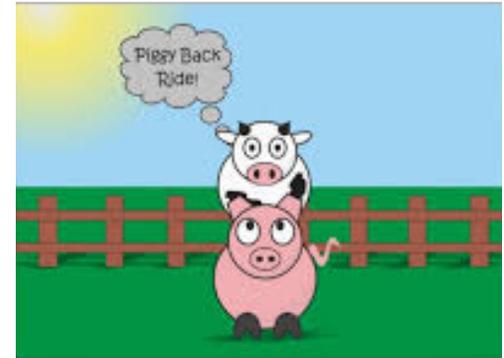


# Article 3(a) – Tabalumab protected by HGS’ patent?

- The Court expressly rejected the infringement test – the fact that marketing Tabalumab during the lifetime of HGS’ patent would infringe is not a crucial factor as to whether the “product is protected”
- Not necessary for active ingredient to be identified in claims by a structural formula (which implies that a structural formula would be OK).
- Can be defined by a functional formula “*on condition that it is possible to reach the conclusion on the basis of those claims, interpreted in light of the description of the invention as required by Art 69 of the [EPC] and the Protocol, that the **claims relate, implicitly but necessarily and specifically, to the active ingredient, which is a matter for the referring court***”
  - Tabalumab not expressly named in the patent nor otherwise specified and so cannot be identified as such
  - “*An active ingredient which is not identified in the claims of a basic patent by means of a structural, or indeed functional definition cannot in any event, be considered to be protected*” for Art 3(a)
- Not so much an “infringement test” as a “falling within the scope of the claims” test – e.g. if there is a patent for a Markush formula which includes A (among millions of other compounds), A will fall within the scope of the claims but A+B will not, even though A+B would infringe this patent.

# Article 3(b) – Can HGS get an SPC on Lilly’s MA?

- Prior to Lilly, it was unclear whether a patent holder could get an SPC based on a third party MA where the MA holder did not consent
- Logic of Biogen supported that it could but seemed harsh on the third party ▶
- Lilly v HGS suggests that such piggy-backing would be contrary to the objectives of the SPC Regulation ▶
- This aspect of the decision was not part of the reference – indeed Warren J. stated expressly that he would not be referring the issue because it was *acte clair* that HGS could obtain the SPC based on Lilly’s MA



Actavis v Sanofi  
Article 3(c) (and 3(a))  
*12 December 2013*

# Actavis v Sanofi – The Facts and the Reference



- Sanofi had a compound patent which claimed irbesartan but also had a claim to “[irbesartan] in association with a diuretic”
- Sanofi had MAs for both irbesartan and irbesartan/HCTZ and obtained two SPCs: irbesartan and irbesartan/HCTZ
- Actavis applied to revoke the irbesartan/HCTZ SPC on two grounds:
  - irbesartan/HCTZ was not “specified” in the claims (Art 3(a))
  - Sanofi had already been granted an SPC for irbesartan based on an MA for irbesartan and this was the “product” of the basic patent; no additional SPCs should be granted in respect of that patent (Art 3(c))
- Arnold J made a reference offering his own solution: whether a product was “protected by a basic patent” should be a question of **substance not form** and should be determined by reference to the “inventive advance (or technical contribution)” of the patent.



# Article 3(a) – is HCTZ specified by a diuretic?

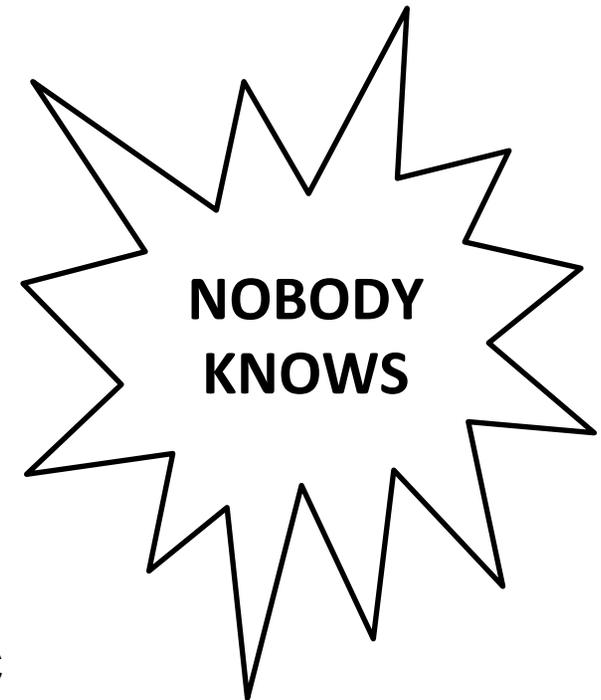
NO

- “Even if... Article 3(a)... were satisfied...” (para 30)

BUT

YES

- ... If Co-Aprovel had been approved first, Sanofi could have chosen an SPC for either irbesartan or irbesartan plus HCTZ (para 38)
- As a practical matter, if Co-Aprovel had been approved first, Sanofi would inevitably seek an SPC for irbesartan alone
- Case ultimately decided on 3(c) (see below)



## Article 3(c) – Irbesartan/HCTZ has not already been the subject of a certificate

- A second SPC for the combination was not permitted under Article 3(c) where the other active ingredient is not protected “as such” by the basic patent
- “*Article 3(c) precludes a patent holder from obtaining, on the basis of one and the same patent, more than one SPC in connection with irbesartan since such SPCs would in fact be connected, wholly or in part with the same product*” (Relying on BASF [2001]?)
- Court concerned about possible evergreening issues – could supplying irbesartan alone infringe an SPC for irbesartan/HCTZ?
- And bases its findings on “policy” grounds: “*the basic objective of Regulation 469/2009 is to compensate for the delay to the marketing of what constitutes the core inventive advance of the basic patent*”.



Georgetown University v  
Octrooicentrum Nederland  
(Article 3(c))

*12 December 2013*

## Georgetown II – the facts, the reference and the ruling

- Georgetown filed a patent in 1993 including claims to HPV-16, HPV-18 and HPV-16 and HPV-18 together
- MAs for Gardasil® in 2006 (HPV-6, HPV-11, HPV-16 and HPV-18) and Cervirax® in 2007 (HPV-16 and HPV-18)
- SPCs **granted** for the two combinations
- Post Georgetown (I), were Georgetown entitled to an SPC for HPV-16 alone?
- Georgetown were prepared to surrender the earlier SPCs but would that work?
- CJEU held that where a patent protects several different products as such the proprietor may obtain an SPC for all such products
- So Georgetown can have an SPC for HPV-16

# Conclusions on Article 3(c) following Sanofi and Georgetown II

- The correct approach appears to be one SPC per product per patent; provided that each product is protected “as such” in the basic patent
- On what basis can it be said that the existence of an SPC for A should prevent an SPC for A+B on the basis of Article 3(c)? It seems to be because the technical contribution was A and that is regarded by the CJEU as the “product” of the patent
- So Arnold J’s approach to 3(a) has been adopted but transplanted to the definition of “product”
- Court looking ahead to Boehringer?
- What has BASF got to do with this?

# Where are we now?

Sub-Section	Current interpretation
a) The product is protected by a basic patent	The product must fall within the scope of the claims – expressly or implicitly but necessarily and specifically (possibly for functional claims only) or “specified/identified in the wording of the claims” (for other types of claim?)
b) Valid authorisation... has been granted	No piggy-backing; with consent, should be OK
c) The product has not already been the subject of a certificate	If an SPC for A is granted, an SPC for B or A+B will only be granted where B or A+B is “protected as such” by the basic patent – so one SPC per product protected “as such” per patent
d) The authorisation in (b) is the first authorisation to place the product on the market	Second medical use SPCs are allowed ( <u>Neurim</u> )

# What does the future hold?

- Actavis v Boehringer Ingelheim (reference by Birss J. dated 23 September 2013)

- Patent amended to claim telmisartan/HCTZ
- Will Boehringer succeed on 3(a) but fail on 3(c)?



- More on active ingredients: Bayer Cropscience (safener); Fosgren (Protein D)
- How will the Courts interpret the new HGS v Lilly test of: “the claims relate, implicitly but necessarily and specifically, to the active ingredient in question”?
- Will clarification be needed on the 3(b) consent issue?

## What does the future hold? (cont.)

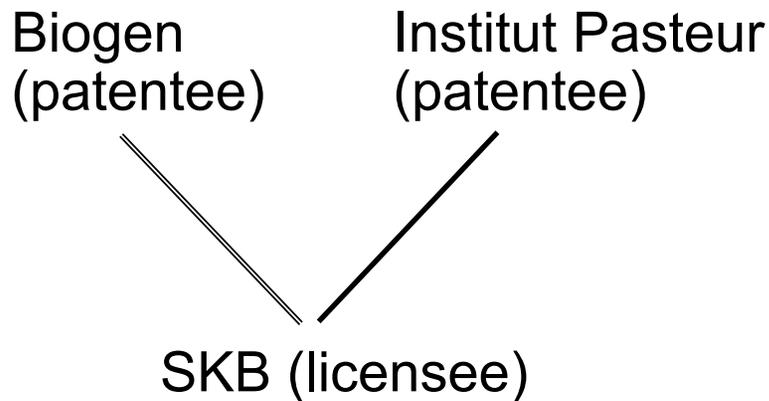
- SPCs and the UPC?
  - 16<sup>th</sup> draft Rules of Procedure of the UPC – SPCs will be opted out if the relevant basic patent is opted out (Rule 5)
  - August 2013, the Commission indicated that the SPC regime would probably not be changed to make it compatible with the UPC. More news promised in November but nothing forthcoming thus far...
- Proposals to reform the SPC Regulation?
  - A number of commentators have indicated that the CJEU wants the Commission to consider reform but nothing yet

## Some Issues for Discussion

- In Lilly, did the Court intend that the “implicitly but necessarily and specifically” test should apply to functional claims only, or across the board?
- Is the “implicitly but necessarily and specifically” test akin to the “inevitable result” doctrine for novelty?
- Are all compounds in a Markush formula specified by the claim?
- Is HCTZ specified by a diuretic?
- Has the CJEU altered the meaning of the product so that it is now “an active ingredient or combination of active ingredients which is protected as such by a patent and which represents a core inventive advance of the patent”?
- Is it true to say that the CJEU is now being driven by the desire to protect innovation (contrast Yissum/MIT with Neurim)?
- Did the CJEU mean to change the law as regards piggy-backing in Lilly? Is it linked to the indication that Tabalumab is not identified in HGS’s patent?

Thank you for your attention

## The Matrix of the Biogen case



- SKB thought (i) only one SPC could be granted per product; and (ii) Biogen's patents were invalid
- SKB had provided IP with a copy of its MA but refused to give it to Biogen
- The Court held that Biogen could obtain an SPC without the relevant MA in its possession



*“... the **refusal** of an SPC application for an active ingredient which is not specifically referred to by a patent ... **may be justified where the holder of the patent ... has failed to take any steps to carry out more in-depth research and identify his invention specifically**, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients. In such a situation, if an SPC were granted to the patent holder, even though – **since he was not the holder of the MA** granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention, that would undermine the objective of Regulation No 469/2009, as referred to in recital 4 in the preamble thereto”.*

