

News from the SPC front

Young EPLAW congress 22 April 2013

Tjibbe Douma

De Brauw Blackstone Westbroek

DE BRAUW
BLACKSTONE
WESTBROEK

Topics

SPCs; what are they and why the commotion?

Scope of protection

Dutch case law post Medeva

Dutch referral to ECJ

2 22 April 2013 Young EPLAW Brussels; News from the SPC front

DE BRAUW
BLACKSTONE
WESTBROEK

Background: SPCs and the SPC Regulation

- Supplementary Protection Certificates (SPCs) are *sui generis* IP rights
- SPCs are intended to compensate pharmaceutical companies for the loss of effective patent term caused by the delay in obtaining regulatory approval for a medicinal product; the delay in obtaining an MA
- The SPC Regulation is meant to harmonise SPC law throughout Europe
(Regulation (EC) 469/2009 of 6 May 2009)



So how did that work out in practice?



- SPCs are applied for nationally (at the Industrial Property Offices, IPO's); this gave rise to different interpretations of the SPC Regulation throughout Europe
- Several questions posed to the CJEU
- Questions centred around conditions for obtaining SPCs (article 3 of the SPC Regulation), in particular for combination products

When can you get an SPC?

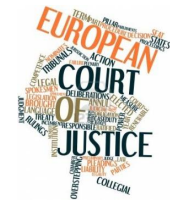
- **Article 3 Conditions for obtaining a certificate**

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 - Medeva (C-322/10)

- *When is the product protected by a basic patent as required by 3(a)?*
- In *Medeva* the CJEU held on 24 November 2011
Article 3(a) of (the) Regulation (...) must be interpreted as precluding the competent (IPO) from granting an SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent (...)
- In three reasoned orders of 25 November 2011 (in *Yeda*, *Queensland* and *Daiichi*) the Court used '**identified**' instead of '**specified**'



CJEU case law on article 3



CASE	Basic Patent Claims:	MA in place for:	SPC possible for:
Medeva	Combination A+B	A +B +C+D Multi-disease vaccine	A+B
Yeda	Combination A+B	A	No SPC possible for A+B
Queensland Several basic patents	1. A+B 2. C 3. D (3 different patents)	A+B+C+D	1. A+B (based on patent 1) 2. C (based on patent 2) 3. D (based on patent 3)
Queensland Product by process	A specified in the wording as (in)direct product of the process claim	A (+B + C)	A
Queensland a contrario Product by process	Process claim. A = product of process but not specified in the wording	A (+B + C)	No SPC possible
Daiichi	A	A+B combination therapy	A

Young EPLAW Brussels; News from the SPC front

Why all the commotion on SPCs?

- SPCs are valuable: they can extend the exclusivity for a product for up to five years after patent expiry
- For blockbusters every day counts for pharmaceutical companies
- Generic companies seize the opportunity; doubt on interpretation of SPC Regulation created strategic possibilities



What do you get with an SPC?



- What is an SPC exactly?
- Does it (in practice) extend the patent?
- What type of supplementary protection do you get and for what?

What does the SPC Regulation say?

Scope of protection of SPCs



- **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 authorised 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.

What does that mean in practice?



- Article 4 limits the protection to the *product* covered by the MA, whereas Article 5 confers on the SPC *the same rights as the basic patent*
- The rationale of course is to compensate for the time it took to get an MA for a specific product
- Does that mean that the supplementary protection is limited to the product covered by the MA?

Novartis v Actavis, CJEU 9 February 2012

Scope of protection of SPCs



- In **Novartis v Actavis** the Court determined that an SPC for A confers the same rights as a patent for A (and thus the SPC for A could be enforced against a product containing A+B).
 - C-442/11 and C-574/11 (English and German referrals)
 - French Supreme Court quashed the decision of the Paris Court of appeal and held on 15 January 2013 that indeed Novartis could (on the basis of the CJEU orders) oppose to a generic version of A+B
- Does this mean that SPCs confer the same rights and have the same scope of protection as the basic patent?

Articles 4 and 5

Scope of protection of SPCs



- In the *Novartis v Actavis* cases the SPCs were granted based on **an MA for A and a patent claiming A** (no mismatch)
- Novartis could also enforce its SPC for A against a generic version of A+B, which was convenient since it did not obtain an SPC for its own A+B product (pre *Medeva*)
- What will happen when an SPC is granted applying the *Medeva*-test in case of a mismatch?

SPCs post *Medeva*; what do you get?



- SPC post *Medeva*
 - MA for A+B (not for A only)
 - Patent for A
 - SPC granted for A
- Can you then enforce an SPC for A against A+C if that is what you could have done on the basis of a patent for A?
- Was that what the CJEU had in mind in solving the mismatches?

SPCs post *Medeva*; what do you get? (ctd.)

- Or should the right conferred by that SPC be limited to just the product covered by the MA, which (delay in obtaining an) MA was the reason you could get an SPC in the first place?
- The crucial part of **Article 4** after all states:
'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 authorised before the expiry of the certificate'

What's next?

- Different national interpretations on CJEU's interpretation of the Regulation
- What do IPOs and national Courts do after *Medeva*?
 - *When will they consider the active ingredient to be specified/identified in the wording of the claims of the basic patent?*



Article 3(a) – the Medeva-test applied

Lundbeck v Generics

- Generics planned to market generic version of Lundbeck's successful antidepressant
- Court of appeal had to decide whether SPC for escitalopramoxolate was valid if this specific salt was not specified in the wording of the process claims
 - Is it enough if it is named in the description as an example-product?



17 22 April 2013 Young EPLAW Brussels; News from the SPC front

Article 3(a) – the Medeva-test applied

Lundbeck v Generics

- With reference to Queensland and the Medeva test, the court held in its decision of 24 January 2012 that the salt escitalopramoxalate, although not named in the wording of the process claim, was sufficiently specified/identified
- Case went to Dutch Supreme Court and opinion by Advocate General was rendered on 8 March 2013, but no grounds seem to have been submitted against this part of the Court of Appeal's decision
 - Judgement expected 14 June 2013 (on validity and on the term 'product' in the sense of article 1 SPC Regulation)



18 22 April 2013 Young EPLAW Brussels; News from the SPC front

DE BRAUW
BLACKSTONE
WESTBROEK

Article 3(a) – the Medeva-test applied

Sanofi v Pharmachemie & Teva



- Sanofi has two SPCs, one for irbesartan (mono) and another for irbesartan in combination with HCTZ (combination) based on separate MAs and based on different claims of the patent
- Combination SPC was (as seen often) valid for some time after the mono SPC lapsed
- The patent did not list HCTZ in the claims nor in the description, just referred to 'a diureticum'
- Generics saw an opportunity; did the combination SPC satisfy the Medeva-test?

Article 3(a) – the Medeva-test applied

Sanofi v Pharmachemie & Teva



- In the UK Actavis initiated "clearing the way" proceedings against Sanofi
 - UK Court decided that new questions should be referred to the CJEU on validity of the SPC
- The Dutch Court in PI proceedings took a practical approach in its decision of 14 September 2012
 - Similar approach was taken in France and Germany
- No time for a referral, PI requested by Sanofi, generics were marketing, SPC about to lapse

Article 3(a) – the Medeva-test applied

Sanofi v Pharmachemie & Teva

- The District Court held that the combination was specified since a man skilled in the art would think of HCTZ as ‘a diureticum’; Medeva-test satisfied, PI granted
- Generics did raise another point: can Sanofi really obtain two SPCs on one patent?
- The Dutch Court again took a practical approach and did not let this get in-between a PI
 - No time for referrals in this case, and referrals already proposed in other Dutch case

21 22 April 2013 Young EPLAW/Brussels; News from the SPC front

DE BRAUW
BLACKSTONE
WESTBROEK

Georgetown University - C-484/12

Art. 3(c) and 14(b)

- District Court of The Hague (21 October 2012)
- Georgetown proprietor of a basic patent which protected four active substances (HPV6, HPV11, HPV16 and HPV18); MA for combination
- Application for a SPC for each of the active substances individually
- Application for HPV16 refused: two certificates already been granted based on the same basic patent (one for the combination of HPV16 and 18, and one for the combination of HPV6, 11, 16 and 18)

22 22 April 2013 Young EPLAW/Brussels; News from the SPC front

DE BRAUW
BLACKSTONE
WESTBROEK

Georgetown University - C-484/12

Art. 3(c) and 14(b)

- District Court of The Hague (21 October 2012)
- **One certificate per patent?**
- ECJ in Medeva: *"In a situation such as in the main proceedings (...) where the patent protects a product, in accordance with article 3(c) of Regulation No 469/2009, only one certificate may be granted for that basic patent"*
- DC: not an 'acte clair'. Easy to circumvent by applying simultaneously for several patents each protecting one single product, instead of protecting several products in one patent



GEORGETOWN UNIVERSITY

Georgetown University - C-484/12

Art. 3(c) and 14(b)

- District Court of The Hague (12 October 2012)
- **Surrender of the earlier certificate**
- Georgetown: retroactive, to be deemed to never have been granted (so the SPC for HPV16 applied for would be the first certificate for the product)
- DC: Art. 14 does not mention retrospective effect; term 'surrenders' must be considered to be a matter of Community law.
- The DC refers five questions to the ECJ



GEORGETOWN UNIVERSITY

Queensland

Art. 3(c) and 14(b)

- Another Dutch referral?
- District Court of The Hague 11 July 2012: University of Queensland / DPO
- Parallel case to Georgetown, same issues, same questions
- Parties got 6 weeks to give their opinion on the proposed questions
- Georgetown case led to an actual referral, but Queensland for reasons unknown not (yet)
- Or just a case of enough is enough?



THE UNIVERSITY
OF QUEENSLAND
AUSTRALIA



DE BRAUW
BLACKSTONE
WESTBROEK

25 22 April 2013 Young EPLAW Brussels; News from the SPC front

Any questions?



Bio-science law review article on recent developments

<http://thespcblog.blogspot.nl/2012/07/recent-developments-new-article.html>

Tjibbe Douma
De Brauw Blackstone Westbroek (NL)

tjibbe.douma@debrauw.com

+31 20 577 1068



DE BRAUW
BLACKSTONE
WESTBROEK

26 22 April 2013 Young EPLAW Brussels; News from the SPC front