Una actualización en materia de Certificados Complementarios de Protección (CCPs) para medicamentos: casos pendientes y examen de algunas decisiones del TJUE y de los tribunales españoles

Lunes de Patentes, Barcelona
23 March 2015

Peter Markvardsen,
European Patent Attorney, Partner

Introduction

- Herein may be used “simplified” (maybe not 100% legally correct) language – this is to make it easier to understand

- Herein included personal comments/opinions are of course open for discussions

- Good academic discussions are one of the very good things of these Pascual Segura organized nice/unique “Los Lunes de Patentes” sessions.

- This discussion of recent CJEU decisions may be seen as a “warm-up” for the subsequent talk of Javier Huarte – which will include his personal experiences in e.g. Spain.

SPC - General

- After expiry (20 years after filing) of a Basic Patent (e.g. EPB1 patent) may be obtained Supplementary Protection Certificate (SPC), which gives maximum 5 years extra protection of the commercial medical product (e.g. a tablet with API) for the MA approved therapeutic indications – accordingly, an SPC is not an extension of the Basic Patent as such, which may cover many other compounds (i.e. other API's)

- There is a lot of money in SPC protection – maybe it is the most valuable protection for originator medical industry, since many drugs sell best in the last years of protection

- Talking to e.g. Head of Patent departments of originator/generic medical companies, the overall impression is that they are happy with the SPC system as such and believes it is clear/simple in most cases (e.g. Basis Patent is a product patent and commercial medical product comprises only one API).

- An SPC is granted by a national/local patent office (e.g. in Spain, Denmark, UK etc) based e.g. an EPB1 patent.

- The SPC system should be "simple" to handle in practice => the national/local patent office examiner should not examine complicated matter – such as e.g. possible equivalent infringement.

- When we get our new nice "EU" Unified Patent Court (UPC – probably in 2016) – I understand that at least for a period it will still be national/local patent offices that will grant SPC.

CJEU - General

- The Court of Justice of the European Union (CJEU) is a generalist Court – i.e. not a specialized patent Court

- Within the Patent "world" it is sometimes popular to criticize CJEU

- I do not think it is so bad – in particular due to CJEU has listened carefully to nice common sense suggestions by referring UK Courts

- One concern/problem is that CJEU a as generalist Court sometimes uses words/terms that are not normally used in specialized Patent Courts – e.g. the famous "specified" term in the Medeva decision

- CJEU respond the questions they get and may be seen as quite focused on resolving the factual case of the lower referring Court.

- In the new nice "EU" Unified Patent Court system, it will be quite rare that CJEU will be involved – I understand that UK has influenced this

- A US Federal Circuit Court judge said that he believes we are doing it right here in Europe – he believes that the US Supreme Court sometimes makes things more complicated than necessary. For business, companies want clear black/white IPR rules and it is not so important if they are 100% fair accordingly to some general "human rights" fairness understanding.

CJEU – Decisions/Agenda

Older “background” decisions:

20060504 **C-431/04 MIT** - *ActiveExcipientNoGood*

20120209 **C-442/11 Novartis** - *ValsartanSPC CoversActavisVal+HCTZ*

20121124 **C-322/10 Medeva** - *SpecifiedInClaims*

20131114 **C-210/13 GSK** - *ConfirmsMITC431-04 HereAdjuvantNoGood*

Relatively recent decisions:

20131212 **C-443/12 Actavis v Sanofi** - *IrbesartanHCTZ CombinationSPCNoGood*

20131212 **C-482/12 Georgetown** - *MedevaVaccine MoreThanOneSPCOKIfDifferentActiveINVENTIVEDrugsInBasisPatent*

20131212 **C493-12 Lilly v HGS** - *Tabalumab LiteralA69ScopeEnough HereSingleProduct ie NotCombinationProduct*

20150115 **C-631/13 Synflorix** - *TwoCovalentAPI – OK*

20150312 **C-577/13** - ActavisBoehringer TelmisartanHCTZ ConfirmedC-433/12 CombinationSPCNoGood

If we have time:

20041019 **C-31/03 Pharmacia** - *CabergolineForUseInMan - NotFirstMAForProduct – EarlierMAForDogs*

20070417 **C-202/05 Yissum** - *CalcitriolForUseInPsoriasis -NotFirstMAForProduct – EarlierMAForRenalFail*

20120719 **C-130/11 Neurim** - *MedicalUseOK*

SPC - Regulation (EC) No 469/2009

Art. 1 **Definitions**	**(a)**: "**medicinal product**": The **sold** marketing authorization (MA) approved **pharmaceutical product** (comprising active ingredient(s) (API) + excipients) for its MA approved therapeutic indications. **(b)**: "**product**": **Active ingredient (API) or combination of active ingredients** of a medicinal product **(c)**: "**basic patent**": The patent used to get the SPC
Art. 3 **Conditions to get a SPC**	**(a)**: the **product is protected by the basic patent** **(b)**: there is a **valid MA to sell the product** as a medicinal product **(c)**: the product has not already been the subject of a certificate (SPC) **(d)**: the **MA in (b) is the first MA** in EU/EEA for the medicinal product
Art. 4 **SPC protection**	Protection of a SPC does **not cover more than basis patent** (e.g. relevant for a RoS method claim) and shall **extend only to the product [API(s)] of the MA and the MA approved therapeutic indications**.

C-431/04 (MIT) - 4 May 2006

- MIT v Bundespatentgericht (Federal Patent Court)

- Basic patent (MIT):
Claims: Covered, the alliance of two elements, polifeprosan ("active" excipient) and carmustine (API) – carmustine earlier used "alone" for treatment of cancer.

- MA (Gliadel):
API: The mechanism of its action consists in the carmustine, a highly cytotoxic active ingredient, being released slowly and gradually by the polifeprosan, which acts as a bioerodible matrix.

- MIT SPC request: SPC be granted for carmustine in combination with polifeprosan

CJEU said:
"product" – Art.1(b): A substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of 'active ingredient', which in turn is used to define the term 'product'.
=> SPC request not allowed

Note: Confirmed in C-210/13 (GSK – 14/11-2013) - adjuvant not Art.1(b) "product"

C-442/11 (Novartis/Valsartan) – 9 February 2012

- Novartis AG v Actavis UK Ltd,

- Basic patent (Novartis):
Claims: Product claims covering valsartan (API) as such
- MA (Diovan, Novartis):
API: Valsartan.
- Novartis granted SPC: SPC for Valsartan

- Actavis generic product: Generic version of Novartis Co-Diovan product - Valsartan in combination with hydrochlorothiazide (HCTZ - a diuretic => also API). Novartis did not apply for an SPC for this later marketed Co-Diovan combination product.

CJEU said:
Referred to earlier case law – an SPC for an Art.1(b) "product" (e.g. Valsartan) covers a "medical product" comprising the "product" (e.g. Valsartan) in combination with one or more other active ingredients (e.g. HCTZ)
=> Actavis generic product infringes Novartis SPC

C-322/10 (Medeva) - 24 November 2011

- Medeva v Comptroller General of Patents (UK)

- Basic patent EP1666057B1 (Medeva):
Claims: Vaccine comprising antigens pertactin (A) and filamentous haemagglutinin (B)

- MA (Infanrix):
API: Antigens A and B + others (c,d,e…etc) – to get a multi-disease vaccine.

- MIT SPC request: SPC be granted for A and B + others (c,d,e..etc)

CJEU said:
Art.3(a): SPC request for A and B + others (c,d,e..etc) not possible, since the others API's (c,d,e…etc) are "not **specified** in the wording of the claims of the basic patent" => rejection of the infringement test in API combination cases, since clear that SPC request (A/B + others) as a medical product would infringe Basic patent (covers product comprising A/B)
Art.3(b): SPC for A and B is OK, since A/B are "specified in the wording of the claims of the basic patent" and it is not a problem that MA also contains others API.
=> Medeva could here get a SPC that covers their MA ("medical product")

C-443/12 (Actavis/Irbesartan HCTZ) – 12 December 2013

- Actavis v Sanofi – *Referring Court (UK)*

- Basic patent EP454511B1 (Sanofi):

Claims: Main product claims covering Irbesartan (API) as such. Dependent claim relates to Irbesartan + “a diuretic”. HCTZ is a diuretic – term not explicitly mentioned in claims/description

- MA (Sanofi):

Aprovel (1997) - API: Irbesartan.

CoAprovel (1998) - API: Irbesartan + HCTZ

- Sanofi granted SPC: SPC for Irbesartan and later SPC for Irbesartan + HCTZ

- Actavis generic product: Generic version of Sanofi CoAprovel (Irbesartan + HCTZ) product. Entry to market after first SPC (Irbesartan alone) expired

C-443/12 (Actavis/Irbesartan HCTZ) (2)
– 12 December 2013

- Actavis v Sanofi

- Referring UK Court (September 2012):

Medeva "specified" test is unclear: The UK Court identified that Medeva "specified in the wording of the claims" test is unclear – illustrated e.g. by that FR Court said CoAprovel is invalid and DE/NL Courts said valid. Decision reads that Medeva is "unclear save in its rejection of the infringement test in combination cases"

Infringement test :

UK Court said that "infringement test proves too much" – i.e. agreed with Medeva in its rejection of the infringement test in API combination cases – accordingly more is required?

C-443/12 (Actavis/Irbesartan HCTZ) (3)

- Referring UK Court (September 2012): Suggested solution to Medeva unclarity:

(76) "What more is required? In my view, the answer is that the product must infringe because it contains an active ingredient, or a combination of active ingredients, which embodies the inventive advance (or technical contribution) of the basic patent. Where the product is a combination of active ingredients, the combination, as distinct from one of them, must embody the inventive advance of the basic patent. Thus in a case such as the present, where the inventive advance of the Patent consists generally of the compounds of formula I, including specifically irbesartan, a medicinal product whose active ingredient is irbesartan is protected by the Patent within the meaning of Article 3(a) because it embodies the inventive advance of the Patent. A medicinal product whose active ingredients are irbesartan and a diuretic such as HCT in combination is not protected by the Patent within the meaning of Article 3(a) because the combination, as distinct from irbesartan, does not embody the inventive advance of the Patent. This is not a question of the wording of the claims of the basic patent, which as discussed above can be manipulated by the patent attorney who drafts it, but of its substance. Thus it would make no difference if claim 20 of the Patent had read "A pharmaceutical composition containing a compound according to any one of claims 1 to 7 in association with HCT". By contrast, if a later inventor were to obtain a patent for an invention consisting of a combination of irbesartan and substance X which surprisingly had a synergistic effect in treating hypertension, then a medicinal product whose active ingredients were irbesartan and X would be protected by that [later] patent since it would embody the inventive advance of that patent. In my view, this interpretation of Article 3(a) would accord with the object of the Regulation, which is to encourage invention in the field of medicinal products by compensating inventors for the delay in exploiting their inventions due to the need to obtain regulatory approval, and not to confer unjustified monopolies."

C-443/12 (Actavis/Irbesartan HCTZ) (4)
– 12 December 2013

- Referring UK Court – Summary of beautiful solution to Medeva “specified” problem

The invention of the Basic Patent relates solely to Irbesartan (API) as such.

HCTZ/diuretic as such is irrelevant for patentability => whether or not HCTZ/diuretic as a combination is included in the description/claims will be based un pure coincidence/luck of the patent draftsman and we can not base our SPC system on such coincidence/luck.

=> In this case SPC for CoAprovel (Irbesartan + HCTZ) is invalid.

C-443/12 (Actavis/Irbesartan HCTZ) (5)
– 12 December 2013

- Referring UK Court – Also said:

(77) “For the avoidance of doubt, this interpretation of Article 3(a) would not prevent a patentee from obtaining an SPC in circumstances where the patent protected a single active ingredient A, but the patentee had only obtained a marketing authorisation for that active ingredient in combination with another active ingredient B. In those circumstances, as the Court of Justice held in *Medeva*, the patentee could obtain an SPC for product A. “

C-443/12 (Actavis/Irbesartan HCTZ) (6)
– 12 December 2013

- CJEU followed the referring UK Court – it reads:

*(29): …*it is possible, on the basis of a patent which protects several different 'products', to obtain several SPCs in relation to each of those different products, provided, inter alia, that each of those products is 'protected' as such [i.e. are Inventive as such] by that 'basic patent"

=> Basic Patent covers e.g. inventive API's A+B as such => this Basic Patent can be used for two different SPC's (i.e. one for A and one for B).

(30): "it cannot be accepted that the holder of a basic patent in force may obtain a new SPC…each time he places on the market ..a medicinal product containing, on the one hand, the principle [inventive] active ingredient [i.e. Irbesartan] [of] basic patent … and another active ingredient [i.e. HCTZ] which is [irrelevant for patentability].

(42): "It follows that .. [SPC regulation] .. precludes a patent holder from obtaining, on the basis of one and the same basic patent, more than one SPC in connection with irbesartan…

On the other hand, if a combination …is the subject of a new basic patent …, the new patent could, in so far as it covered a totally separate innovation, confer entitlement to an SPC for that new combination that is subsequently placed on the market.

=> CJEU decided that Sanofi CoAprovel (Irbesartan + HCTZ) SPC is invalid

C-577/13 (Actavis/Telmisartan HCTZ) – 12 March 2015

- Actavis v Boehringer – *Referring Court (UK)*

- Basic patent EP502314B1 (Boehringer, filed 1992):

Claims: Granted B1 had main product claims covering Telmisartan (API) as such.
Description explicitly describes combination Telmisartan + HCTZ => made amended UK dependent claims explicitly including this combination.

- MA (Boehringer):

Micardis (1998) - API: Telmisartan
MicardisPlus (2002) - API: Telmisartan + HCTZ

- Boehringer granted SPC: SPC for Telmisartan *(Basic Patent – Granted B1)* and later SPC for Telmisartan + HCTZ *(Basic Patent – Amended UK)*

- Actavis generic product: Generic version of Sanofi MicardisPlus (Telmisartan + HCTZ) product. Entry to market after first SPC (Telmisartan alone) expired

C-577/13 (Actavis/Telmisartan HCTZ) (2) – 12 March 2015

- Actavis v Boehringer – *Referring Court (UK)*

- CJEU decision – confirmed C-443/12 (Actavis/Irbesartan HCTZ):

Article 3(a) and (c) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 16 May 2009 concerning the supplementary protection certificate for medicinal products 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 [here Telmisartan], 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 [here HCTZ], that provision precludes the holder from obtaining a second supplementary protection certificate for that combination.

=> Boehringer MicardisPlus (Telmisartan + HCTZ) SPC is invalid

C-493/12 (Lilly/Tabalumab) – 12 December 2013

- Eli Lilly v Human Genome Sciences (HGS) – *UK referring Court*

- Basic patent EP939804B1 (HGS):

Claims: Product claims related to a antibody that binds to Neutrokine alpha. Lilly antibody Tabalumab binds to Neutrokine alpha. The claims/description does not describe the Tabalumab amino acid sequence – i.e. not explicitly described in the HGS Basic patent.

- MA:

No HGS MA – Lilly fears that HGS may get SPC based on Lilly MA for Tabalumab. Lilly expressly admits that Tabalumab infringes claims of HGS Patent.

- Lilly request to Court : A possible SPC using HGS patent as Basic Patent should be invalid

- Lilly argument: HGS claim covers “millions” of antibodies and Tabalumab is not “specified in claims” in view of Medeva, since no a structural definition.

- Note: This case relates to a single API and not a combination of two or more API’s

C-493/12 (Lilly/Tabalumab) (2) –
12 December 2013

- Question to CJEU:

In essence, whether Article 3(a) .. must be interpreted as meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force.., the active ingredient must be identified in the claims of the patent by a structural formula, or whether the active ingredient may also be considered to be protected where it is covered by a functional formula in the patent claims.

- CJEU said:

Infringement test: Confirmed that infringement test is not enough => not always enough to have only broad functional definition (i.e. no structural definition)

Decided: "it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active ingredient is covered by a functional formula …, Article 3(a) ..does not.. preclude the grant of a SPC .., on condition that it is possible to reach the conclusion on the basis of those claims, …that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court."

C-493/12 (Lilly/Tabalumab) (3) –
12 December 2013

- 18 July 2014 – UK referring Court decision:

Decision:

"There is no doubt that tabalumab is an antibody which binds to Neutrokine-a or the extracellular domain of Neutrokine-a. There is also no doubt - at least it is accepted by Lilly for the purposes of the present application - that tabalumab falls within claim 13 properly interpreted. It is not simply that sales of tabalumab would infringe claim 13. In my judgment, claim 13 "relates" to tabalumab and does so "implicitly but necessarily and specifically". Accordingly, Lilly's application for a [invalidity] declaration fails."

Personal comments:

To be practical "implicitly but necessarily and specifically" may be said to be clearly literally infringement – i.e. no room for e.g. equivalent infringement.

The SPC system must be "simple" to handle in practice => the national/local patent office examiner should not examine complicated equivalent infringement matter.

In practice – there will normally be clearly literally infringement, since generic products generally directly "copy" the API.

I understand that the Lilly UK case has been appealed.

C-484/12 (Georgetown/HPV's) – 12 December 2013

- Georgetown University v Octrooicentrum Nederland [NL Patent Office)

- Basic patent EP647140B1 (Georgetown):

Claims: Claim 1 relates generically to "(PV) L1 protein" antigen (inducing antibodies against papillomavirus) and dependent claims, wherein the "(PV) L1 protein" is HPV-6, HPV-11, HPV-16, HPV-18 or HPV-16 and HPV-18 together.

- MA:

Sanofi, Gardasil® (20/9-2006) - API: HPV-6, HPV-11, HPV-16 and HPV-18
GlaxoSmithKline, Cervarix® (20/9-2007) - API: HPV-16 and HPV-18

- Georgetown SPC request: Eight requests – including all four (i.e. Sanofi), the two of GSK plus the HPV API's individually

- NL patent office (pre Medeva):

Granted: "HPV-6, HPV-11, HPV-16 and HPV-18" (Sanofi) + "HPV-16 and HPV-18" (GSK)

HPV-16 alone based on Gardasil®: Rejected pre Medeva and after Medeva question was if is OK in view of Art.3(c) – i.e. "HPV-16 alone" first SPC?

C-484/12 (Georgetown/HPV's) (2) – 12 December 2013

- Question 1:

In essence, whether, ..on the basis of a basic patent and an MA in respect of a medicinal product consisting of a combination of several active ingredients, the patent holder has already obtained an SPC for that combination of active ingredients, …must be interpreted as precluding that patent holder from also obtaining an SPC in respect of one of those active ingredients …, individually, by that patent.

- CJEU decided:

Also HPV-16 alone is OK: SPC regulation does not preclude Georgetown from also getting "HPV-16 alone" based on same Basic Patent and same MA (even though they already have an "HPV-6, HPV-11, HPV-16 and HPV-18" SPC based on Gardasil®.

=> Extra SPC for "HPV-16 alone" OK based on first MA (Gardasil®).

C-631/13 (Synflorix/Protein D) -
15 January 2015

- Arne Forsgren v Österreichisches Patentamt

- Basic patent EP0594610B1 (A. Forsgren):
Protein D: surface exposed protein of *Haemophilus influenza*
Claims: Protein D as such/product + vaccine with Protein D

- MA (Synflorix vaccine of GlaxoSmithKline):
API: *Streptococcus pneumoniae* polysaccharide serotypes [antigens] covalenlty conjugated to Protein D (*as carrier protein*).
Indications: Vaccine against diseases caused by *S. pneumonia*
MA states*:* "There is insufficient evidence that Synflorix provides protection against ...*Haemophilus* influenzae"

- SPC request: SPC for Protein D

C-631/13 (Synflorix) (2)

- API: *S. Pneumonia* antigen covalently bound to Protein D (as carrier protein) – i.e. It could be considered as ONE subtance/compound with two different API‘s

- Question 1:

In essence, whether Articles 1(b) and 3(a) of SPC Regulation must be interpreted as precluding the possibility that an active ingredient can give rise to the grant of an SPC on the sole ground that the active ingredient is covalently bound to other active ingredients forming part of a medicinal product.

- CJEU said:

Art 1(b): In view of C-431/04 (MIT), the term ‘active ingredient’ concerns substances producing a therapeutic action of their own and Art 1(b) does not say anything about “covalently bound” => this matter as such is not appropriate to exclude the grant of an SPC.

=> SPC OK in this case if Protein D is an API on it own.

C-631/13 (Synflorix) (3)

- API: *S. Pneumonia* antigen covalently bound to Protein D (as carrier protein)

- Question 2(a):

In essence, whether Article 3(b) of SPC Regulation precludes the grant of an SPC for an API whose therapeutic effect does not fall within the therapeutic indications covered by the wording of the MA.

Forsgren (GSK) argued:

As e.g. explained in basic patent, Protein D confer protection against infections caused by Haemophilus influenza => it is an API in view of Art.1(b).

The fact that the MA for Synflorix does not mention that therapeutic effect is irrelevant.

- CJEU said:

SPC system must be "simple" to handle in practice: "the [SPC] system…is intended to establish some simplicity and some transparency" => can not require that local/national patent office have to look in other sources than the MA to identify whether the substance at issue is an API.

Art. 4: Says SPC protection covers only the MA approved therapeutic indications => not get a SPC for an API whose effect does not fall within the therapeutic indications of the MA.

=> SPC not allowable based on Protein D effect against Haemophilus influenza

C-631/13 (Synflorix) (4)

- API: *S. Pneumonia* antigen covalently bound to Protein D (as carrier protein)

- Question 2(b):

In essence, whether a carrier protein [Protein D] conjugated to a pneumococcal polysaccharide used in a vaccine may be regarded as a "product" (API)

Forsgren (GSK) argued:

Unconjugated polysaccharide [antigen] vaccines do not work (not inducing an immunogenic response) - on the other hand where polysaccharide antigens are conjugated with a carrier protein, they may induce such effects.

- CJEU said:

Not 100% identical to C-431/04 (MIT) and C-210/13 (GSK): MIT related to excipient and GSK to adjuvant – here it is a carrier. One may say that in MIT/GSK the API would have therapeutic effect without excipient/adjuvant – just less good. In this case, there is no effect without the carrier.

But essentially confirmed MIT/GSK: Also a carrier is only "product" (API), if it has a therapeutic effect of its own, which is covered by the MA.

=> In this case CJEU said referring court must judge this.

C-31/03 (Pharmacia) - 19 October 2004

- Pharmacia Italia v Bundesgerichtshof (Germany)

- Basic patent DE3112861 (Pharmacia):
Claims: Product claims covering API Cabergoline

- MA:
(Dostinex, Pharmacia, 1992) - API: Cabergoline for a use in human
(Galastop, 1987) - API: Cabergoline for a use in dog

- Pharmacia SPC request: SPC be granted for Cabergoline

CJEU said:
"product" - First MA: The veterinary/dog MA is first MA for the "product" (API) Cabergoline
=> SPC request not allowed

C-202/05 (Yissum) - 17 April 2007

- Yissum v Comptroller-General of Patents (UK)

- Basic patent (Yissum):
Claims: Topical calcitriol (API) composition for psoriasis

- MA :
(Silkis®, Galderma Ltd, 2001) - API: Topical calcitriol composition for psoriasis
(Calcijex®, Earlier than 2001): - API: Calcitriol sterile aqueous solution for intravenous injection and is used for the management of hypocalcaemia.
(Rocaltrol®, Earlier than 2001): - API: Calcitrio gelatine capsules administered orally to patients with chronic renal failure.

- Yissum SPC request based on Silkis®: Primarily SPC for calcitriol - Alternatively, Yissum requested an SPC for a combination of calcitriol with an ointment/topical base.

CJEU said:
"product" – Art.1(b): "the concept of 'product' cannot include the therapeutic use of an active ingredient protected by a basic patent => case where a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product.
=> SPC request not allowed

C-130/11 (Neurim) - 19 July 2012

- Neurim v Comptroller-General of Patents (UK)

- Basic patent EP518468B1 (Neurim – filed 1992):

Claims: Melatonin (a natural hormone) has not as such been patented => claims related to a new melatonin controlled-release formulation suitable for treatment of insomnia/sleeplessness.

- MA :

(Circadin®, Neurim, 2007) - API: Melatonin for treatment of insomnia/sleeplessness.
(Regulin®, Hoechst, 2001) - API: Melatonin for use in sheep.

- Neurim SPC request based on Circadin®: SPC for Melatonin.

C-130/11 (Neurim) (2) - 19 July 2012

- Earlier pre Neurim understanding:

It was generally thought that an SPC was precluded (or its duration was truncated) if the API in question had any earlier MA, even if the earlier MA related to a different medical use in a different species

- Neurim change – get SPC on new second medical uses:

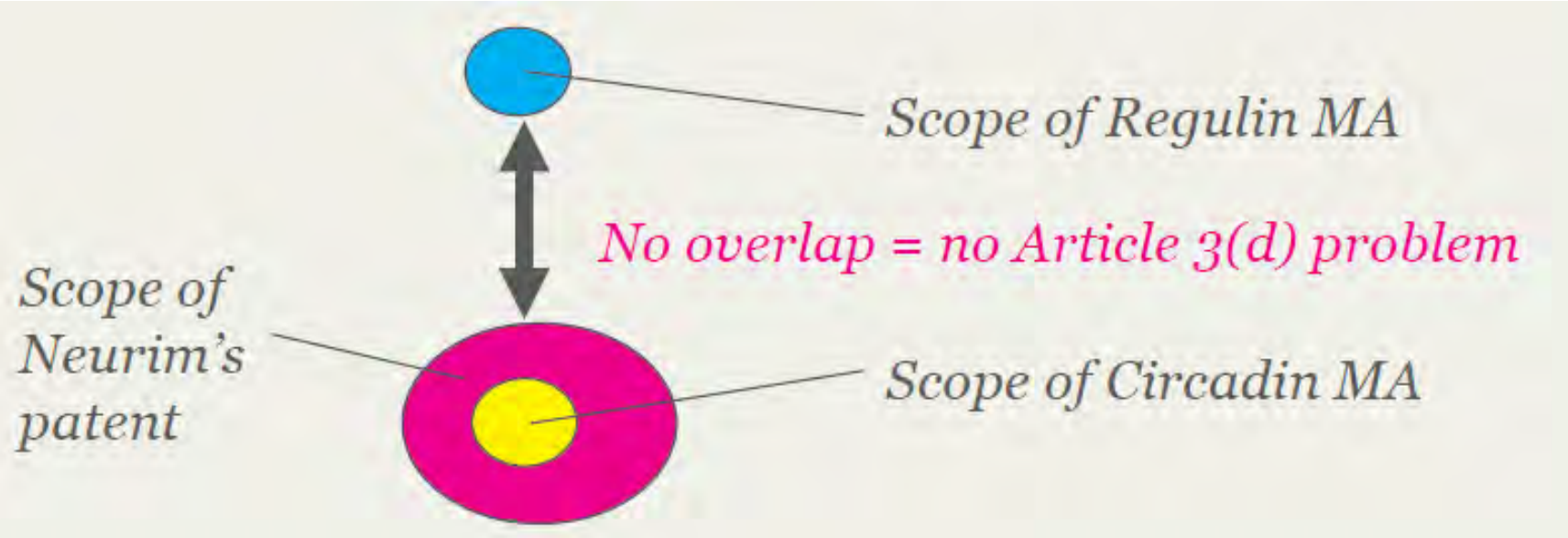
Neurim clarifies that is not always the case

-Pharmacia (C-31/03) and Yissum (C-202/05):

These earlier decisions had focused on the definition of the "product" (API as such) in order to distinguish the later authorization from the earlier one.

-Neurim arguments focusses on the scope/claims of the Basic Patent:

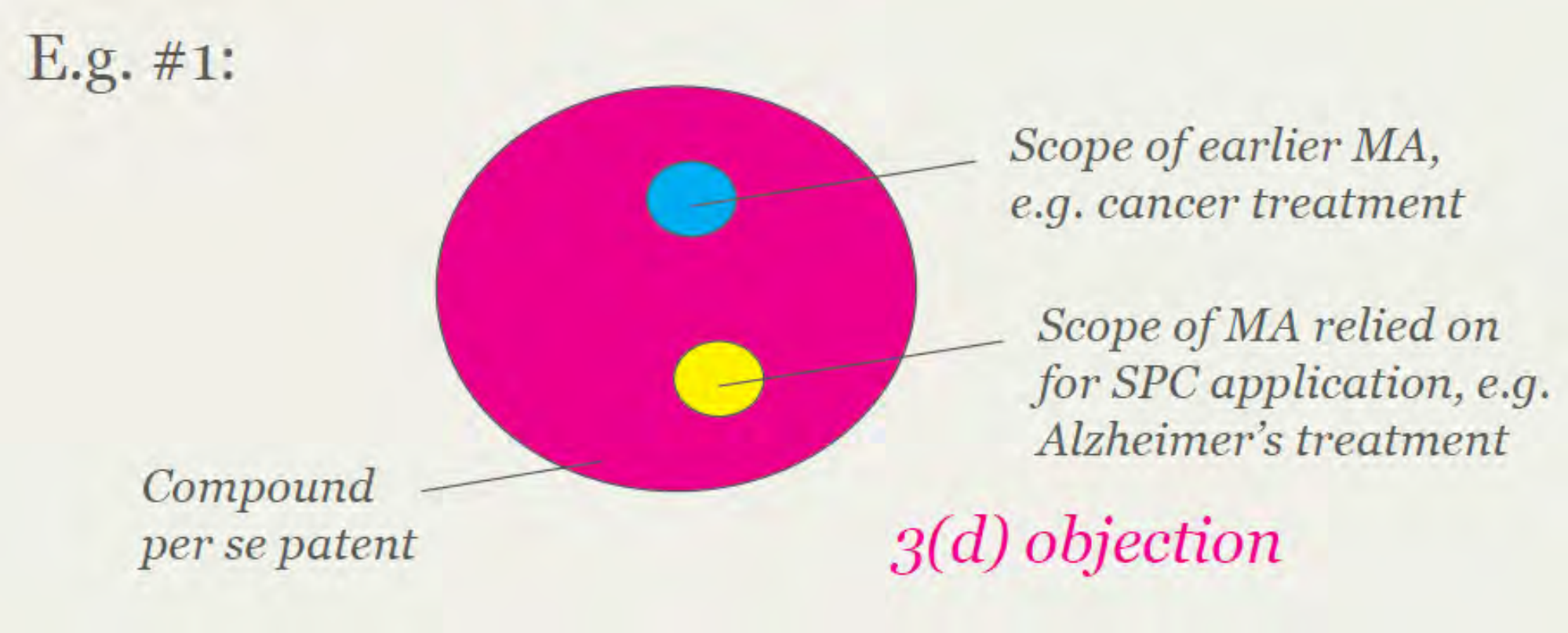
Does the earlier authorization fall within the scope of the claims of the basic patent?



C-130/11 (Neurim) (3) - 19 July 2012

- What did Neurim argue?

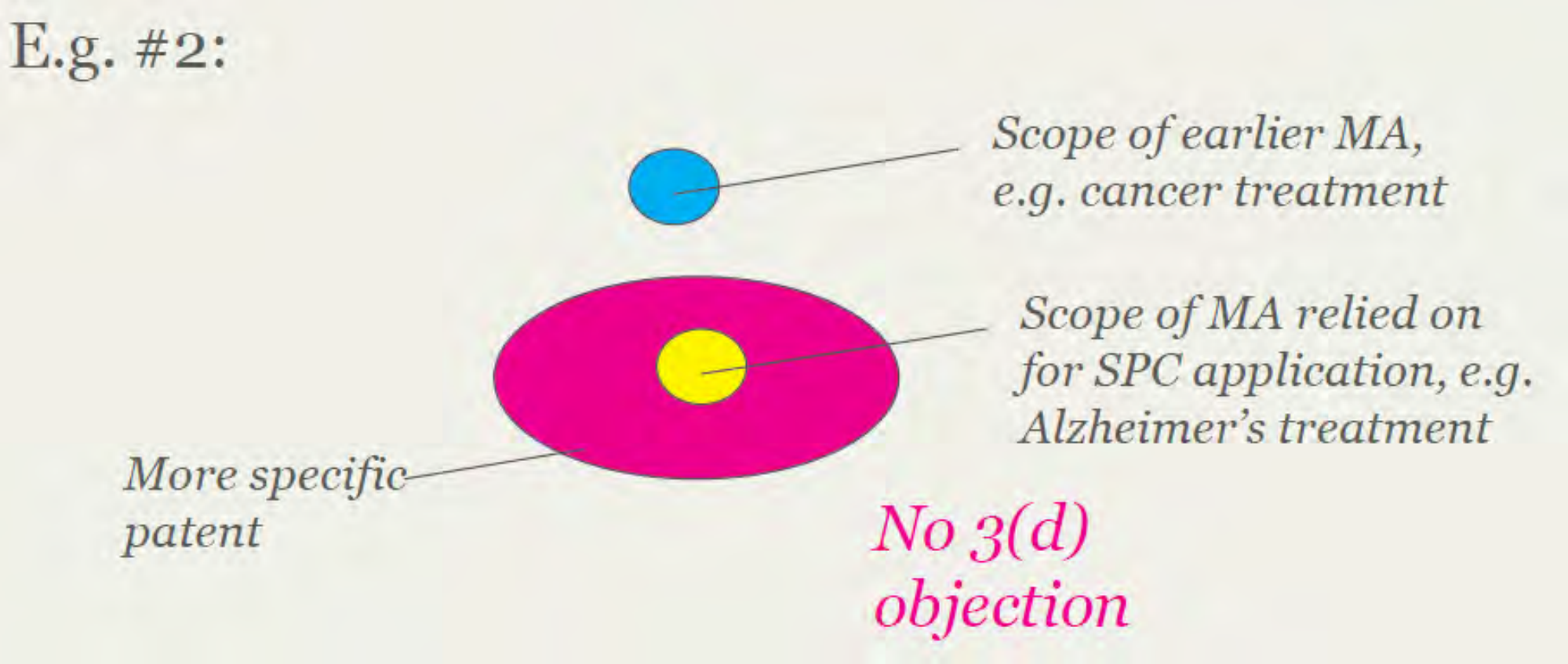
Only if the earlier MA allowed its holder to work within the scope of the patent should the MA count under Article 3(d).



C-130/11 (Neurim) (4) - 19 July 2012

- What did Neurim argue?

Only if the earlier MA allowed its holder to work within the scope of the patent should the MA count under Article 3(d).



C-130/11 (Neurim) (5) - 19 July 2012

- Referring UK Court – Question 1:

"In interpreting Article 3 of [the SPC Regulation], when [an MA] (A) has been granted for a medicinal product comprising an active ingredient, is Article 3(d) to be construed as precluding the grant of an SPC based on a later [MA] (B) which is for a different medicinal product comprising the same active ingredient where the limits of the protection conferred by the basic patent do not extend to placing the product the subject of the earlier MA on the market within the meaning of Article 4?"

-CJEU essentially agreed with Neurim arguments and said:

"25 Therefore, if a patent protects a therapeutic application of a known active ingredient which has already been marketed as a medicinal product, for veterinary or human use, for other therapeutic indications, whether or not protected by an earlier patent, the placement on the market of a new medicinal product commercially exploiting the new therapeutic application of the same active ingredient, as protected by the new patent, may enable its proprietor to obtain an SPC, the scope of which, in any event, could cover, not the active ingredient, but only the new use of that product.

"26 In such a situation, only the MA of the first medicinal product, comprising the product and authorised for a therapeutic use corresponding to that protected by the patent relied upon for the purposes of the application for the SPC, may be considered to be the first MA of 'that product' as a medicinal product exploiting that new use within the meaning of Article 3(d) of the SPC Regulation…

C-130/11 (Neurim) (6) - 19 July 2012

- Referring UK Court – Question 2:

"If the grant of the SPC is not precluded, does it follow that in interpreting Article 13(1) [Duration of the certificate] of the SPC Regulation, "the first [MA] in the Community" needs to be an authorisation to place a medicinal product on the market within the limits of the protection conferred by the basic patent [used to get the SPC] within the meaning of Article 4?"

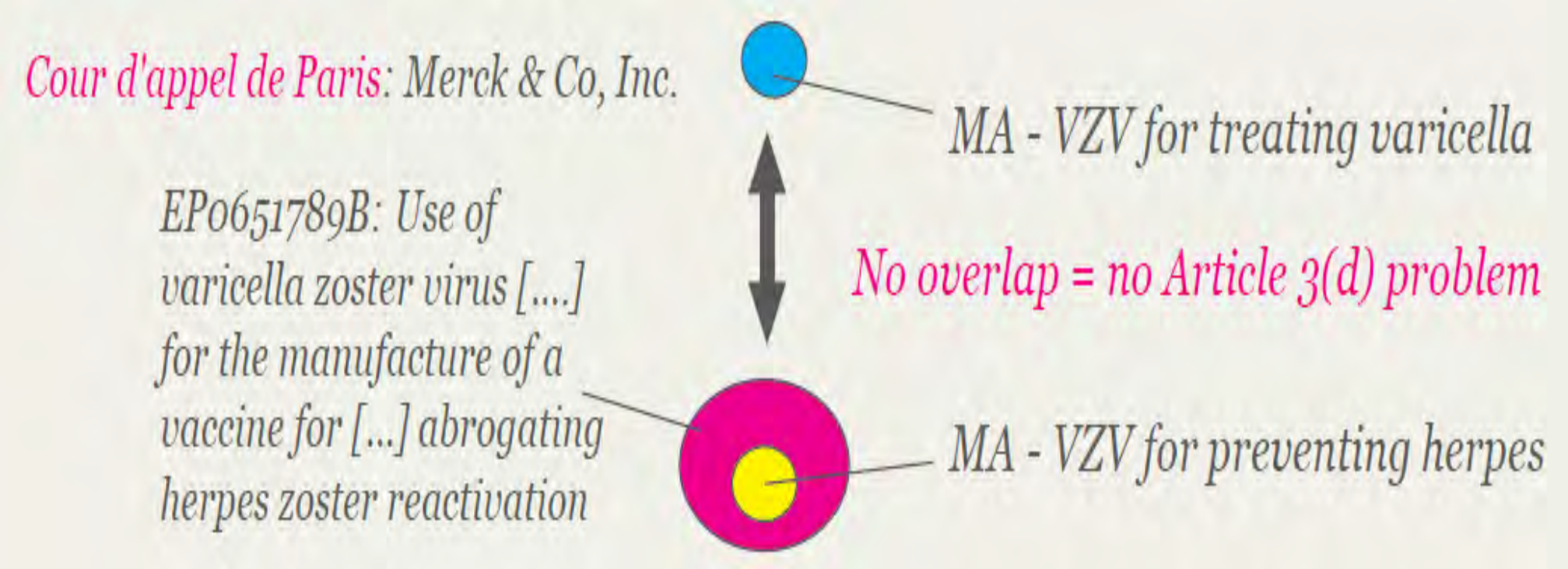
-CJEU said:

"30 … Therefore, the MA referred to in Article 13(1) [i.e. first MA] of the SPC Regulation is the authorisation of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC."

=> Since first MA within the scope of Neurim "treatment of sleeplessness" Basic Patent (filed 1992) was their own Circadin® MA they got a SPC that lapses 2017.

C-130/11 (Neurim) (7) - 19 July 2012

- Post Neurim grant of SPC (lapse 2018) for e.g. EP651789B1 (Merck, filed 1993):



Short Summarizing Comments

- Single API MA/SPC:

For those of us who are old enough – we recall that pre Medeva (before 2011) were granted a number of SPC's (e.g. to Biologics/Antibodies) based on Basic Patents with functional claim language.

Accordingly, it may be said that C-493/12 (Lilly/Tabalumab) essentially has put us back to pre-Medeva times – i.e. one may get a SPC when there is clearly literally infringement.

-Combination MA/SPC – Inventive API + API irrelevant for patentability:

Medeva and post Medeva Actavis decisions (C-443/12 + C-577/13) have significantly changed the situation – earlier granted Irbesartan + HCTZ SPC was invalidated in C-443/12 and Telmisartan + HCTZ SPC was invalidated in C-577/13.

Annex – List of decisions

20041019 **C-31/03 Pharmacia** *CabergolineForUseInMan - NotFirstMAForProduct – EarlierMAForDogs*

20060504 **C-431/04 MIT** *ActiveExcipientNoGood*

20070417 **C-202/05 Yissum** *CalcitriolForUseInPsoriasis -NotFirstMAForProduct – EarlierMAForRenalFail*

20120209 **C-442/11 Novartis** - *ValsartanSPC CoversActavisVal+HCTZ*

20120719 **C-130/11 Neurim** *MedicalUseOK*

20120920 **UKCourt** *C443-12 ActavisvSanofi IrbetasanHCTZ QuestionsToECJ*

20121124 **C-322/10 Medeva** *SpecifiedInClaims*

20131114 **C-210/13 GSK** *ConfirmsMITC431-04 HereAdjuvantNoGood*

20131212 **C-443/12 Actavis v Sanofi** *IrbesartanHCTZ CombinationSPCNoGood*

20131212 **C-482/12 Georgetown** *MedevaVaccine MoreThanOneSPCOKIfDifferentActiveINVENTIVEDrugsInBasisPatent*

20131212 **C493-12 Lilly v HGS** *Tabalumab LiteralA69ScopeEnough HereSingleProduct ie NotCombinationProduct*

20140718 **UKCourt** *AfterC-493/12 LillyHGS Tabalumab – SPCOK*

20150115 **C-631/13 Synflorix** - *TwoCovalentAPI – OK*

20150312 **C-577/13** - ActavisBoehringer TelmisartanHCTZ ConfirmedC-433/12 CombinationSPCNoGood