

# Three CJEU decisions that answer some questions but pose many more

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## Supplementary protection certificates

Since 1993, supplementary protection certificates (SPCs) have been Europe's answer to the patent term extensions (PTEs) that are available in the USA and Japan. In common with PTEs, SPCs are intended to provide an additional period of protection, beyond normal patent expiry, for certain regulated products. In the EU, these regulated products are medicines (human and veterinary) and so-called 'plant protection products' (agrochemicals and the like).

Nevertheless, although serving a similar primary purpose to PTEs (ie encouraging innovation by providing a sufficient duration of post-marketing exclusivity), SPCs were created with a uniquely European flavour. Thus, for example, an SPC does not extend the term of a patent, but instead provides protection only in respect of authorized uses of the active ingredient(s) defined as the 'product' for the SPC.

## Background to the three cases

The cases decided on 12 December 2013 were C-443/12 *Actavis v Sanofi*; C-484/12 *Georgetown University v Octrooiencentrum Nederland*; and C-493/12 *Eli Lilly v HGS*.

In addition to the date upon which they were decided, a common feature of the three cases was that they arose from the failure of previous judgments of the Court of Justice of the European Union (CJEU) to provide sufficient clarity on issues fundamental to the validity of many SPCs.

In essence, the judgments addressed the following questions.

1. Is it possible to use one patent as the basis for more than one SPC?

For many years, the common practice of patent offices had been to grant only one SPC per product to a single patentee. This is because Article 3(c) of Regulation 469/2009 requires that 'the product has not already been the subject of a certificate'. However, that common practice did not prevent the granting of multiple SPCs

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## This article

- On 12 December 2013, the Court of Justice of the European Union (CJEU) issued judgments in three cases that raised fundamental questions regarding the operation of the system of supplementary protection certificates (SPCs) in Europe.
- These judgments provide patent offices and national courts across Europe with important guidance on the circumstances under which SPC protection will be available. This guidance appears to set a higher standard with regard to the strength of the connection that is required between the nature of the active ingredient(s) that are authorized for sale and the 'core inventive advance' of the patent upon which the supplementary protection is based.
- While providing a modicum of clarification, the 12 December judgments appear to follow in the footsteps of other of the CJEU's recent judgments in raising more questions than they answer. With this in mind, the various national patent offices and courts may well struggle to interpret parts of the CJEU's rulings, or apply them to cases having different fact patterns. This is likely to lead to still further questions being referred to the CJEU on related points. However, given the sheer number of difficult questions that could now arise, it might also lead to questions about whether 'tweaking' the SPC legislation would be preferable to repeatedly presenting the CJEU with the increasingly challenging task of interpreting the present legislation in a clear, coherent and fair manner.

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to the holder of a patent that protected multiple (authorized) products.

Before the cases reported in this article, the validity of this practice was never the subject of any questions put to the CJEU. Nevertheless, doubt was cast upon that practice through (non-binding) comments made by Advocate-General Verica Trstenjak. That is, in Joined Cases C-322/10 *Medeva* and C-422/10 *Georgetown University and others*,<sup>1</sup> Advocate-General Trstenjak commented, in connection with Article 3(c), that ‘according to the Court’s case law, only one supplementary protection certificate may be granted for each basic patent’.

2. Article 3(a) of Regulation 469/2009 requires that ‘the product is protected by a basic patent in force’, but what are the criteria for deciding whether this provision has been satisfied?

For a number of years, different Member States of the EU had adopted divergent practices on this particular point. Indeed, for that very reason, questions on this point had already been posed to the CJEU (including in *Medeva*). However, the ‘test’ emerging from the judgments of the CJEU left a lot to be desired. This is because it did not take long for cases to come before the national courts where it was not at all clear whether the active ingredient(s) in question were ‘specified’ (or ‘identified’) in the wording of the claims of the basic patent.

## Question 1

As explained below, question 1 arose in connection with both *Actavis v Sanofi* and *Georgetown University*.

### *Actavis v Sanofi*

Sanofi was the proprietor of a patent (EP 0 454 511 B1) that protected the compound irbesartan. The patent also contained a claim to a composition comprising irbesartan in association with ‘a diuretic’.

In 1997, Sanofi obtained a centralized marketing authorization for Aprovel, a medicinal product containing irbesartan as the sole active ingredient. Just over a year later, Sanofi obtained a centralized marketing authorization for CoAprovel, which contained both irbesartan and hydrochlorothiazide (HCTZ, a diuretic) as active ingredients.

Based upon the same patent, Sanofi obtained separate SPCs in the UK for irbesartan (SPC/GB98/037), and the combination of irbesartan and HCTZ (SPC/GB99/008).

Because of the later approval date for CoAprovel, the term of the SPC for the combination product expired more than a year later than the term for the single agent SPC.

Seeking to market a generic version of CoAprovel, Actavis sought revocation of SPC/GB99/008. One of the grounds of revocation relied upon by Actavis was non-compliance with Article 3(c), due to the prior granting of an SPC based upon the same patent.

### *Georgetown University*

Georgetown University was the proprietor of a patent (EP 0 647 140 B1) claiming vaccines containing certain human papilloma virus (HPV) L1 proteins.

Upon the basis of centralized marketing authorizations for Gardasil (a vaccine containing HPV-6, HPV-11, HPV-16 and HPV-18 L1 proteins) and Cervarix (a vaccine containing HPV-16 and HPV-18 L1 proteins), Georgetown University filed a number of SPC applications in the Netherlands.

SPC applications directed towards the combinations of HPV proteins present in Gardasil and Cervarix were granted in 2008. However, the progress of Georgetown’s other SPC applications, directed towards single active agents (eg HPV-16 or HPV-18), was stalled until the CJEU confirmed (in *Georgetown University*) that it can be permissible to direct an SPC application to a single active agent even where that active agent has only ever been authorized for use in combination with other active ingredients.

The CJEU’s decision in C-422/10 allowed Georgetown’s single active SPC applications to clear one hurdle. However, the lack of clarity in relation to whether multiple SPCs could be granted based upon one patent prompted the Dutch patent office to refuse the application to HPV-16 L1 protein.

## Question 2

This question was at issue in both *Actavis v Sanofi* and *Eli Lilly v HGS*.

### *Actavis v Sanofi*

A further ground upon which Actavis sought revocation of SPC/GB99/008 was an alleged failure of the basic patent to satisfy the requirements of Article 3(a) in relation to the combination of irbesartan and HCTZ. In this respect, Actavis asserted that the term ‘diuretic’ did not sufficiently specify HCTZ in the wording of the claims.

<sup>1</sup> Joined Cases C-322/10 *Medeva* and C-422/10 *Georgetown University and others* [2011] ECR I-12051 and [2011] ECR I-12057.

## Eli Lilly v HGS

HGS was the proprietor of a patent (EP 0 939 804 B2) directed towards the protein Neutrokine- $\alpha$ , and antibodies to it. After having been unsuccessful in attempts at the EPO and the UK courts to revoke the patent, Eli Lilly acknowledged that marketing in the UK of an antibody that they had developed (tabalumab) would infringe Claim 13 of HGS's patent. However, Eli Lilly sought from the UK High Court a declaration that any SPC based upon HGS's patent and a marketing authorization for tabalumab (if and when such an authorization was granted) would be invalid. Eli Lilly based their allegation of invalidity upon the assertion that the broad, functional definition of antibodies in Claim 13 of HGS's patent contained insufficient structural information for the conclusion to be reached that the active ingredient tabalumab was 'specified in the wording of the claims' (thus failing the test set by the CJEU in *Medeva*).

## The CJEU decisions

### Answers to question 1

The table below summarizes the outcomes of the decisions in connection with question 1 (Article 3(c)).

It can thus be seen that, despite the superficially similar factual situations, the CJEU reached different decisions in the two cases addressing Article 3(c).

Considering only the wording of the CJEU's ruling in *Actavis v Sanofi*, the decisive factor against permitting two SPCs based upon the same patent appears to have been the absence of any patent claim covering HCTZ alone.

Further, although not mentioned in the operative part of the judgment, an ancillary consideration in *Actavis v Sanofi* appears to have been the later expiry of the SPC

to the combination of irbesartan and HCTZ (relative to the expiry of the SPC to irbesartan).

The court's comments on this point appear to indicate their belief that, if a single active ingredient (eg irbesartan) has already been the subject of SPC protection, a *later-expiring* SPC to the combination of that active with another active ingredient, based upon the same patent, will *not* be permissible if that second active ingredient is 'not protected as such by the basic patent'.

One reason behind the court's belief appears to have been the fact that, if the breadth of the claims of the basic patent permits, an SPC to a single active ingredient can be used to oppose the marketing of (medicinal) products containing that active ingredient alone *or in combination with any other active ingredients*. In other words, the CJEU appeared to feel that the SPC to irbesartan (alone) had already given Sanofi a sufficient period of supplementary protection for the combination of irbesartan and HCTZ.

In this respect, the CJEU indicated that (further) SPC protection is awarded as compensation for delays to the marketing of what constitutes 'the core inventive advance' that is the subject of the basic patent. Following the guidance of the referring (UK) court, the CJEU appeared to be of the view that the 'core inventive advance' in Sanofi's patent was irbesartan, and not the combination of that active ingredient with HCTZ.

With regard to *Georgetown University*, the ruling in Georgetown's favour appears to have focused on slightly different criteria. There, the CJEU placed emphasis upon the fact that Georgetown's patent protected not only two combinations of active ingredients (HPV L1 proteins types 6, 11, 16 and 18, or types 16 and 18) but also the single active ingredient that was the subject of the pending SPC application (ie HPV-16 L1 protein).

Patentee	Active(s) claimed in patent	SPC product definitions	Date of EC MA Decision	>1 SPC per patent OK?
Georgetown	A1 (or B1, C1 or D1)	A1	20 Sep 2007	Yes
	A1 + B1	A1 + B1	20 Sep 2007	
	A1 + B1 + C1 + D1	A1 + B1 + C1 + D1	20 Sep 2007	
Sanofi	A2	A2	27 Aug 1997	No
	A2 + B2	A2 + b2	15 Oct 1998	

#### Key

A1=HPV16 L1 protein

B1=HPV18 L1 protein

C1=HPV6 L1 protein

D1=HPV11 L1 protein

A2=irbesartan

B2='a diuretic'

b2=hydrochlorothiazide

Curiously, this fact does not appear to provide a clear distinction over *Actavis v Sanofi*. However, it is possible that the CJEU had in mind a further fact, namely the existence of ‘as such’ patent protection for each of the individual active ingredients of the two combinations. Although potentially providing a distinction over *Actavis v Sanofi*, mention of this fact is conspicuously absent from the CJEU’s judgment.

In this respect, there is a possible alternative reason for the different conclusions reached in the two cases. That is, in contrast to the situation in *Actavis v Sanofi*, all of Georgetown’s SPC applications were based upon marketing authorizations issued upon the same date. As commented in point 35 of the reasons for the decision in *Georgetown University*, this has the following consequence:

Even if the protection conferred by two such SPCs were to overlap, they would, in principle, *expire on the same date*’ (emphasis added).

## Answers to question 2

Although posed to the CJEU in *Actavis v Sanofi*, question 2 was not answered in that case. However, through tacit admissions relating to the products protected by the patent (in point 28 of the reasons for the decision), the CJEU in *Actavis v Sanofi* did appear to be prepared to accept that the claim to a composition comprising irbesartan and ‘a diuretic’ does ‘protect’ a product defined as the combination of irbesartan and HCTZ.

The *possible* acceptability of ‘functional’ definitions of active ingredients emerges much more clearly from the decision in *Eli Lilly v HGS*. In that case, the court started out by explaining the reasons why it is necessary to determine ‘protection’ for an active ingredient by reference to the claims (and to national or European provisions governing interpretation of the claims), and why recourse may *not* be had to the rules governing infringement proceedings. Having established those points, the court stated, in points 38 and 39 of the reasons for the decision:

38. It should be recalled that . . . an active ingredient which is not identified in the claims of a basic patent by means of a structural, or indeed a functional definition cannot, in any event, be considered to be protected within the meaning of Article 3(a) of Regulation 469/2009.

39. With regard to the question of whether the use of a functional definition alone may be sufficient, it should be noted that Article 3(a) of Regulation 469/2009 does not, in principle, preclude an active ingredient which is given a

functional definition in the claims of a patent issued by the EPO being regarded as protected by the basic patent.<sup>2</sup>

From these comments, it appears that the CJEU has clarified that, in order to satisfy the requirements of Article 3(a), the claims of the basic patent must contain an integer (be it a structural or functional definition) that reads on to the active ingredient in question.

Unfortunately, however, the CJEU added a caveat to this conclusion:

[O]n condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the EPC and Protocol on the interpretation of that provision, that *the claims relate, implicitly but necessarily and specifically, to the active ingredient in question.*<sup>3</sup> [Emphasis added]

The potential importance of this caveat, which is also recited in the operative part of the CJEU’s judgment, emerges in point 43 of the reasons for the decision, which states:

[T]he refusal of an SPC application for an active ingredient which is not specifically referred to by a patent issued by the EPO relied on in support of such an application may be justified . . . where the holder of the patent in question 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.<sup>4</sup> [Emphasis added]

Thus, although it might not be clear what the CJEU meant by ‘implicitly but necessarily and specifically’, it does seem that there is likely to be significant variability with regard to the ability of an SPC applicant to rely upon claims that functionally define an active ingredient. Further, some of that variability could derive from the different levels of involvement that different SPC applicants will have had in the in-depth research that enabled identification of the specific active ingredient(s) concerned.

## Commentary

### Question 1: commentary

Considering only the operative parts of the judgments, there is *arguably* an inconsistency between the decision in *Actavis v Sanofi* and that in *Georgetown University*. This is because the CJEU in *Georgetown University* did

<sup>2</sup> *Eli Lilly v HGS* (C-493/12).

<sup>3</sup> *Ibid.*

<sup>4</sup> *Ibid.*

not mention patent protection for the ‘secondary’ ingredient of the combination product as a relevant criterion for their (favourable) decision. By way of contrast, this criterion was absolutely central to the (unfavourable) decision in *Actavis v Sanofi*.

Although this makes the two decisions difficult to reconcile, patent offices and courts are likely to be guided by the discussion of the reasons for the decision in *Actavis v Sanofi*. In other words, they may well take note of the reasoning that points to the ‘core inventive advance’ of a basic patent as being an important factor in the granting of SPC protection.

Nevertheless, and in common with the unsatisfactory prior decisions of the CJEU that led to the need to refer still further questions to the CJEU in *Actavis v Sanofi* and *Georgetown University*, even a detailed analysis of the CJEU’s reasoning leaves many questions still unanswered.

For example, in paragraph 42 of the reasons for the decision in *Actavis v Sanofi*, the CJEU appears to imply that, even if an SPC to active ingredient A has been granted, a *later-expiring* SPC to the combination of A+B can be granted if based upon a ‘new basic patent’ that covers ‘a totally separate innovation’. This then opens up further questions, such as the following.

- (i) Does there need to be a ‘new basic patent’ if it can be shown that combination relates to ‘a totally separate innovation’ from the single active?
- (ii) What are the criteria for judging when there is ‘a totally separate innovation’? For example, is mere separate patentability under European standards enough, or must the two innovations be non-unitary relative to one another in view of the prior art? Alternatively, must the combination be innovative over the single active ingredient (eg under a standard akin to that used for assessing obviousness-type double patenting under US law)?
- (iii) Does it make a difference if the two SPCs (to A and A+B) would have the same expiry date?
- (iv) Does it make a difference if two SPCs based upon the same patent do not overlap? For example, although an SPC to A can be used to oppose the marketing of a (medicinal) product containing A+B, the same cannot be said for an SPC to A+C. Thus, for example, is it permissible to obtain SPCs to both A+B and A+C when those SPCs are based upon a patent for which active ingredient A is the ‘core inventive advance’?

With respect to point (iii) above, the decision in *Georgetown University* would tend to suggest that the answer is ‘yes’. However, there do not appear to be clear answers to any of the other points.

Answers to all of the above questions will be required in order to enable broad applicability of the CJEU’s decisions. In the author’s view, it is therefore inevitable that national patent offices and courts will yet again find themselves in positions where the case law of the CJEU does not provide clear answers to fact patterns that differ in one or more potentially significant respects from previously decided cases.

## Question 2: commentary

No doubt many national patent offices and courts will welcome the clarification provided by the CJEU with regard to the potential acceptability of functional definitions of active ingredients. However, their gratitude to the CJEU may extend no further than that. This is because, in the author’s view, the caveat to the CJEU’s answer (that the claims must relate ‘implicitly but necessarily and specifically’ to the active ingredient in question) provides yet another test that will be almost impossible for the national patent offices and courts to apply to cases having different fact patterns.

The new questions that arise in connection with the CJEU’s ruling and commentary in *Eli Lilly v HGS* are too numerous to mention. However, it may be that one of the most urgent questions arising from that case will not relate to interpretation of the SPC legislation but to the nature of the legislation itself. This is because it appears that, for the purposes of assessing eligibility for SPC protection in cases involving ‘functional’ definitions of active ingredients, national patent offices and courts will now need to consider the level of involvement of the applicant in ‘in depth research’ into the authorized active ingredient. If this is so, those offices and courts may prefer instead to turn their attention to the question of whether the current SPC legislation meets one of its fundamental objectives of providing ‘a simple, transparent system which can easily be applied by the parties concerned’.

## Summary and practice points

Although certain aspects of the three decisions of the CJEU may have surprised some commentators, their core themes do appear to have been foreshadowed in the rulings of *Medeva* and *Yeda*,<sup>5</sup> which were decided in late 2011. Thus, for example, this author was one of the

5 C-518/10 *Yeda* 2011 I–12209.

co-authors of a report<sup>6</sup> on cases including *Medeva* and *Yeda* that surmised the following:

The first point is that the active ingredient(s) may be sufficiently 'specified' (or 'identified') in the claims of the basic patent without being named explicitly as individual compounds. The second point is that it seems that the Court of Justice may have intended to allow a product to be defined as multiple active ingredients only in the circumstances where that combination of ingredients represents an innovation that is distinct from each of the active ingredients on its own. In the instances where the true innovation lies in only one of the active ingredients, SPC protection can be applied for (and obtained) on the basis of that single ingredient.<sup>7</sup>

We now know the first of these points to be true, albeit with an unexpected (and unworkable) caveat for functionally defined compounds.

Further, although the second point relates to Article 3(a), it bears a striking similarity to key aspects of the ruling in connection with Article 3(c) in *Actavis v Sanofi*. If this similarity is no coincidence and actually reflects the fundamental principles underlying the CJEU's judgments, then this might suggest various practice points, including the following.

- (i) It ought to be possible to use a single patent to obtain SPCs to both A and A+B, *provided that* it can be shown that the combination relates to an innovation that is distinct from the single active ingredient.
- (ii) In this respect, the CJEU's comments about the requirement for a 'new basic patent' may be misleading. On the other hand, it may be that filing a divisional application in order to obtain separate protection for the combination may not overcome the Article 3(c) problem if the combination truly does not represent an innovation that is distinct from the single active.
- (iii) Where an innovative active ingredient is first marketed in combination with one or more other

active ingredients, it would be prudent to seek an SPC for that innovative active (or each innovative active) on its own.

- (iv) This is because the alternative strategy of seeking SPC protection for multiple, non-overlapping combinations containing the same active ingredient *may* be problematic in view of Article 3(c) unless each such combination can be shown to represent a distinct innovation.

Because the guiding principles behind the various CJEU judgments are still not entirely clear, it is not yet possible to say whether points (i) and (ii) above represent 'best practice' for designing an SPC strategy. However, unless and until the CJEU's guiding principles become known, (i) and (ii) above are certainly practices that it would at least be wise for the SPC applicant to consider.

This lack of certainty and clarity will be frustrating not only for SPC applicants but also for the national patent offices and courts that are tasked with interpreting the CJEU's decisions and applying the principles derivable from them to a wide range of fact patterns. It might be unfair to blame the CJEU for this situation, as it should be remembered that they face what has undoubtedly become an extremely challenging task, namely the interpretation of the present legislation in a clear, coherent and fair manner. In this respect, there may be some users of the SPC system who will now start to question whether 'tweaking' of the SPC legislation would be preferable to endless rounds of questions being referred to the CJEU.

Nevertheless, considering that it has not been long since the SPC legislation was last reviewed (and consolidated), a more likely outcome is that further questions will soon be referred to the CJEU in order to seek clarification on one or more of the many unclear points of the recent judgments. It is difficult to predict the ultimate outcome if and when such further questions are referred, except perhaps to say that the answers are unlikely to be the final word on the increasingly complex world of SPCs.

<sup>6</sup> M Snodin, J Miles and M Pears 'Supplementary Protection Certificates: The CJEU Issues its Decision in Two Seminal Cases' (2012) 12 *Bio-science Law Review* 58.

<sup>7</sup> See note 3.