Making sense of the recent CJEU decisions on Supplementary Protection Certificates (SPCs)

In four important cases, the CJEU ruled that in most circumstances multiple SPCs for different products may be obtained under a single patent. The CJEU also provided further guidance on the type of patent claims that can support an SPC.

Background

Supplementary Protection Certificates (SPCs) exist to compensate patentees in Europe for the long time it can take to get pharmaceutical products to market. SPCs are available for medicinal products and can be extended when the product has been tested for paediatric use.

This system allows a patentee for a patented pharmaceutical product to obtain an extension of protection, beyond the patent term, for up to 5 years.

In order to obtain an SPC, the product of the SPC must contain an active ingredient or a combination of active ingredients. That product must be protected by a basic patent and be the subject of a marketing authorisation in the country or countries of interest.

A number of prior CJEU decisions looked specifically at the situation surrounding products containing a combination of active ingredients.

In some instances, the marketing authorisation related to a product which did not have the same active ingredients as those protected by the patent. The CJEU decided that, in cases of such a mismatch, an SPC can still be directed to the patented active ingredients.

If the patent protects only A, an SPC can be directed to A, even if the marketing authorisation is for A + B. Where a marketing authorisation is for A + B + C, but the patent only protects A + B, the SPC can be for A + B, and so on.

The table below provides a summary of the situations in which an SPC is possible:

Patent	SPC	MA	Allowed?
A	A	A	YES
A	A+B	A+B	NO
A	A	A+B	YES
A	A	A+B+C+...	YES
A+B	A+B	A+B	YES
A+B	A+B	A+B+C+...	YES
A+B	A+B	A	NO
A+B	A	A	NO

In those decisions, the CJEU stated that the test for determining whether a product is protected by a basic patent is to ask if the product is "specified" or "identified" in the wording of the claims of the basic patent.

However, the Court did not explain how much detail was needed for the product to be "specified" or "identified".

By way of example, prior to those rulings, the UK Intellectual Property Office (UK-IPO) has granted an SPC for the product A + B where the patent claimed A, together with a carrier and, optionally, other therapeutic ingredients. The UK-IPO deemed that the claims covered A + B even though B was not explicitly recited.

It is questionable whether the UK-IPO would now grant such an SPC, in particular whether it would deem B to be "specified" in that claim. Whether a claim to A in

combination with an antibody (where B is a known antibody) would be considered to protect A + B is similarly uncertain.

The CJEU did give some guidance, however. It stated that, if a patent claims a product having two active ingredients, but does not claim an active ingredient individually, an SPC cannot cover that ingredient alone.

Since those decisions, a number of national Courts have tried to apply this test and found that serious questions still arose as to the boundaries of the test.

In the prior decisions, the CJEU had also cast uncertainty on how many SPCs are allowed per patent. For many years national authorities have allowed multiple SPCs for single patents, based on the understanding that it is possible to have one SPC *per product*, per patent. However, the CJEU chose not to confirm whether or not this approach was correct or whether national authorities should only allowed one SPC per patent regardless of how many products are protected by the patent.

These uncertainties led to the referrals, which resulted in the four important cases being handed down by the CJEU in December 2013:

Actavis Group v Sanofi(C-443/12)

Eli Lilly v HGS(C-493/12)

GeorgetownUniversity(C-484/12)

Glaxosmithkline Biologicals SA(C-210/13)

Does an active ingredient need to be identified in the claims by a structural formula or will a functional formula suffice?

In the Lilly case, the CJEU was asked whether an SPC is possible where the product is an antibody which is defined in the claims of the basic patent in functional terms (antibody binding to a particular target antigen).

The CJEU decided that for a product to be protected by a basic patent in force, it is not necessary for the active ingredient to be identified in the claims by a structural formula.

Where the active ingredient is covered by a functional formula in the patent claims, it may be possible to obtain an SPC, provided that the claims, when interpreted in the light of the description relate "implicitly but necessarily and specifically" to the active ingredient.

The CJEU has left the interpretation of the claims to the national Courts. Therefore, we will have to wait and see how the national Courts decide whether the claims relate "implicitly but necessarily and specifically" to the active ingredient. For many cases, it is difficult to see how this should be interpreted at a general level and is thus likely to come down
to a case-by-case basis.

Is an adjuvant an active ingredient?

In the Glaxosmithkline case, the CJEU decided that adjuvants do not fall within the definition of "active ingredients" and so cannot be the product of an SPC.

This is the case even if the adjuvant influences the therapeutic effect of an active ingredient, because the adjuvant ahs no therapeutic effect on its own and so cannot be the subject of an SPC either alone or in conjunction with an active ingredient, such as an antigen.

Is it possible to obtain multiple SPCs for different products based on the same basic patent?

In the Georgetown case, the CJEU was asked whether multiple SPCs can be granted based on a single patent for different products, and whether an applicant can surrender an earlier granted SPC if they are only allowed one SPC perpatent. Similar questions were asked in the Actavis case.

Georgetown's SPC applications related to cervical cancer vaccines (Gardasil® and Cervarix®) comprising multiple antigens, where each antigen was described for the first time in the basic patent. Georgetown had applied for multiple SPCs on the basis of this single patent for the antigens alone and various combinations of the antigen, based on the same marketing authorisation. Therefore, all the SPCs would expire at the same time because the duration of the SPC is calculated by subtracting the filing date of the basic patent from the date of first marketing authorisation in the Community minus five years, with the maximum term being 5 years (plus a possible 6 month paediatric extension). Georgetown had been granted SPCs to various combinations of antigens, but wanted SPCs to the single antigens on the basis of the same patent, because the CJEU has previously ruled that an SPC for a single active ingredient can be infringed not only by a drug containing that ingredient, but also by a combination drug containing the ingredient. If they were not allowed to do that, they asked whether they could surrender their combination product SPCs in favour of the single product SPCs.

In the Actavis case, Sanofi's SPCs related to a combination of an antihypertensive agent (irbesartan) together with a diuretic (HCTZ). The patent claims included one directed to "irbesartan in combination with a diuretic", but nowhere in the claims or the patent description was HCTZ specifically recited. Sanofi had already been granted an SPC for irbesartan alone and was seeking an SPC for the combination with HCTZ on the basis of the same patent. The marketing authorisation for the combination with HCTZ was granted some time after that for irbesartan alone, such that the combination SPC would expire 14 months later than that to irbesartan alone.

In Georgetown, the CJEU decided that, it is possible, in principle, to obtain multiples SPCs for different products where a single patent protects a number of different products, provided that each of the products is protected as such by the basic patent.

Therefore, Georgetown should be allowed multiple SPCs for the single antigens and combinations of antigens that are protected as such by the same basic patent, with those SPCs all expiring on the same date.

If the marketing authorisation for the single active ingredient had been granted after a marketing authorisation for a combination of actives including that single active, it seems that 2 SPCs could be granted on the basis of the same basic patent, 1 for the single active and 1 for the combination. However, those SPCs would both expire on the same date because the first marketing authorisation for the combination of actives, which contains that active would be used to calculate the SPC duration, not the later marketing authorisation for the single active. The exception here would be where the active ingredient contained in the later marketing authorisation is different to that contained in the earlier marketing authorisation and both fall within the limits of protection conferred by the basic patent. In the Georgetown case, the HPV-16 antigen contained in the earlier marketing authorisation for Gardasil® is different to the HPV-16 antigen contained in the later marketing authorisation for Cervarix®, and both forms appear to be protected by the basic patent.

However, in the Actavis case, the CJEU outlined an exception to this principle, which arises in the situation of Sanofi's SPCs. Where a basic patent protects both a first active ingredient and a combination of that active ingredient together with another, and an SPC has already been granted for the first active ingredient on the basis of a relevant marketing authorisation, an SPC for the combination product cannot be obtained under the same basic patent on the basis of a later marketing authorisation.

The CJEU stated in the decision that a new SPC, potentially for a longer period of protection, cannot be obtained each time a medicinal product containing the principle active ingredient, protected as such by the basic patent and constituting the core inventive advance of that patent, is placed on the market in combination with another active ingredient which is not protected as such by that patent.

Therefore, Sanofi should not be allowed a combination SPC as they already have a single active SPC under the basic patent. Thus, Sanofi cannot benefit from the additional 14 months of protection afforded by the later marketing authorisation for the combination. Instead, the SPC for the single active covers the single active product and combination product under the one SPC, but expires on the earlier date.

At first, it may appear possible to circumvent this issue by filing separate patents (e.g. divisionals) to new active ingredients and related combination products. However, the CJEU specifically stated that each separate patent can only confer entitlement to a new SPC insofar as it covers "a totally separate innovation".

The CJEU failed to define what they meant by "totally separate innovation", so it will be up to the national Patent Offices and Courts to determine this. Ultimately, another referral to the CJEU asking how to determine this is likely.

Conclusions

The CJEU decisions were heavily based on the particular factual scenarios in which the references were made, making it difficult to extrapolate principles that can be applied more generally.

What we can determine from the decisions is that, adjuvants are not considered active ingredients and so cannot be the product of an SPC.

With the exception of certain circumstances, such as Sanofi's combination SPC, multiple SPCs for different products should be possible on the basis of a single patent. However, a decision on whether those multiple SPCs are worthwhile needs to be balanced with a determination of the SPC term. For example, where the patent protects A and A + B, the SPC term for SPCs to A and A + B will be the same if the first marketing authorisation encompasses A + B (e.g. A + B, A + B + C, etc.). In terms of infringement, the SPC for A can be infringed not only by a drug containing A, but also by a combination drug containing the ingredient, such as A + B. Thus in that situation, 2 SPCs may not be necessary. If the first marketing

authorisation is only for product A, and the combination product A + B is later authorised, an SPC for A + B with a later expiry date seems to only be possible if the SPC applicant can convince the patent office that A + B is a "totally separate innovation" to A alone.

The Georgetown decision provides some relief for SPC owners who, in situations like those in Georgetown, will not need to forfeit second and subsequent SPCs on the same basic patent.

Active ingredients claimed in functional terms rather than purely structural terms, particularly antibodies defined by their binding to a particular antigen, should be sufficient for the purposes of SPC protection. More clarity is still needed on what is meant by "implicitly but necessarily and specifically" in terms of active ingredients other than antibodies, which are defined functionally.

In terms of making sure the claims of the basic patent "protect" the product of the SPC, it is still difficult for SPC holders to formulate a strategy that deals with the increasingly confusing SPC decisions coming from the CJEU. One point that is clear is that patentees should aim to include claims to the product (whether that is a single active or combination of actives) on a general level, along with increasing levels of specificity before grant. Any likely commercial products should specified in as much detail as possible in the dependent claims so that the national patent offices do not struggle to determine if the product is "implicitly but necessarily and specifically" claimed.