Obtaining SPC's, the saga continues

The Court of Justice of the European Union (CJEU), the highest court in Europe, has been asked to explain further how to obtain Supplementary Protection Certificates (SPCs) for combination products.

In its previous decisions in two similar cases, *Medeva*and *Georgetown et al*. (reported here), the CJEU decided that the product, "protected by" the patent, isspecified in the claim wording. However, the CJEU did not explain how much detail was needed for the product to be "specified" in the claim wording. Therefore, there have been a number of conflicting decisions on the interpretation of the CJEU decision in Europe.

These previous decisions also have an impact on single product SPCs because the same principle applies - the single product must be "protected by" the patent.

The questions referred

Due to the uncertainty, the UK Patents Court in two cases has asked the CJEU what the criteria are for deciding whether a (single or combination) product is "specified" in the claim wording.

The Court is also seeking clarification on whether it is possible to obtain multiple SPCs on a single patent where the patent protects multiple products. It had previously been thought that multiple SPCs for single patents are allowable provided each SPC is directed to a different product. However, some doubt had been cast on this interpretation during the*Medeva* and *Georgetown et al*. proceedings.

A further question has arisen as to whether a person is permitted to obtain an SPC based upon a marketing authorisation obtained by another.

Background to the referrals

Actavis v Sanofi

The Patents Court had to decide on the validity of Sanofi's combination product SPC.

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Sanofi had two SPCs based on a single patent. There was no dispute over the first SPC for irbesartan alone, which expired on 14 August 2012. Actavis argued that the second SPC for irbesartan in combination with the diuretic hydrochlorothiazide (HCTZ) indicated for hypertension was invalid because this combination was not protected by the patent.This SPC does not expire until 14 October 2013 because the marketing authorisation for the combination was granted later than for the single active.

The patent claims cover irbesartan and also pharmaceutical compositions containing irbesartan in combination with various active ingredients described generically by reference to function, one of which was with a diuretic. HCTZ is a commonly used diuretic for hypertension, but the patent does not mention HCTZ.

Therefore, the question was whether this claim adequately "specified" this combination. The Court decided that the CJEU had not given enough information in their previous decision to enable them to answer this question, and so has asked the CJEU what the criteria are for deciding whether a product is "specified" in the claim wording.

The Court offered their view on how they believe the question should be answered by looking to the inventive contribution of the patent. The Court decided that the inventive contribution resided in irbesartan itself not its combination with a diuretic. Therefore, the Court did not believe that the patent protected the combination.

Eli Lilly v HGS

The Patents Court was asked to decide whether a single product SPC can be granted to HGS based on Eli Lilly's marketing authorisation.

Eli Lilly had a UK marketing authorisation for the antibody LY2127399 that binds to the Neutrokine-α polypeptide. HGS had a patent that they believed covers Eli Lilly's antibody.

Eli Lilly was concerned that HGS might seek an SPC based on Eli Lilly's own marketing authorisation, so filed a pre-emptive request at the Patents Court to make an immediate reference to the CJEU to prevent this.

Eli Lilly disputed the validity of the SPC on the grounds that:

1. the patent granted to HGS did not "protect" Eli Lilly's authorised antibody; and
2. it is impermissible for a person to apply for an SPC based on a marketing authorisation obtained by another.

Eli Lilly argued that the HGS patent claim (a) provides no specified primary antibody sequence and (b) fails to disclose any functional information besides the broad assertion that the antibody binds full length hTNFSF13b or its extracellular domain. Therefore, even though the product falls within the scope of the claims, the product is not "specified" in the wording of the claims.

On the second ground, Eli Lilly argued that the SPC Regulation was created to compensate a party for the regulatory delaysthey faced in bringing a pharmaceutical product onto the market. However, HGS has suffered no such delay as they were taking advantage of Eli Lilly's marketing authorisation.

As with *Actavis v Sanofi*, the Court decided that the CJEU had not given enough information in their previous decision to enable them to decide whether a product is "specified" in the claim wording. Therefore, on 10 October 2012 the Court decided to also refer questions to the CJEU on this point. The precise questions to be referred have not yet been formulated.

The Court also decided that a person can apply for an SPC based on a marketing authorisation obtained by another. The Court considered this issue to be clear enough not to be referred to the CJEU by itself. However, since other questions are being referred on the specification issue, the Court may choose to include a question on this point.

Conclusion

The CJEU decision on these matters will have an impact on both combination and single product SPCs. Hopefully, the CJEU will provide more detailed criteria on the level of specification required for the product to be "protected" by the basic patent.

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The decision should also clear up questions concerning how many SPCs can be obtained per patent for multi-product patents and whether a person can apply for an SPC based on a marketing authorisation obtained by another.

We await the CJEU decision with interest.

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