Novartis decision completes a new model for SPCs in EU

A new European court decision completes a new model of how both availability and breadth of protection under supplementary protection certificates are to be assessed. Its confirmation of an earlier decision means SPCs will be afforded a broader scope than some had previously appreciated, report ***Mike Snodin*** and ***Michael Pears***.

The Court of Justice of the EU has been busy issuing decisions that signal fundamental changes to the general understanding of key aspects of the supplementary protection certificate legislation[1].

For example, in November 2011, decisions in *Medeva* and *Georgetown University et al* (cases C-322/10 and C-422/10, respectively) changed the understanding of two provisions that govern the availability of SPCs[2,3]. Most recently, the CJEU has issued a decision[4], in *Novartis v Actavis* (case C-442/11), that will change the general understanding of the scope of protection of an SPC.

This decision goes hand-in-glove with aspects of the *Medeva* and *Georgetown University et al* decisions, and hence completes a new model for interpretation and practical application of the SPC legislation. Its confirmation of the interpretation of SPC scope used in the *Medeva* and *Georgetown University et al* cases means that all national patent offices and courts are now formally bound to apply this interpretation, and thereby afford SPCs a broader scope than some had previously appreciated.

Novartis held an SPC in the UK for the "product" valsartan. That SPC was based upon:

- a patent protecting the "product" (as required by Article 3(a) of the SPC legislation); and
- a marketing authorisation for the "product" (as required by Article 3(b) of the SPC legislation).

The marketing authorisation relied upon was that for Diovan, a medicinal product containing valsartan as the sole active ingredient.

In some countries (but not in the UK), Novartis had obtained a separate SPC for a "product" defined as a combination of valsartan and hydrochlorothiazide (HCTZ). Such SPCs were supported by marketing authorisations granted in respect of the medicinal product Diovan HCT, which contains both valsartan and HCTZ.

Such additional SPCs can sometimes be permitted under the SPC legislation. This is because a single active ingredient (eg A) is deemed to be a different "product" to a combination of active ingredients (eg A+B).

Against this background, Actavis sought to launch a generic version of Diovan HCT after expiry of Novartis's UK patent protecting valsartan but before expiry of Novartis's UK SPC to valsartan.

In asserting its right to do this, Actavis essentially argued that:

- Article 4 of the SPC legislation states that the scope of protection afforded by an SPC extends "only to the product covered by the authorisation"; and
- the "product" for Novartis's SPC in the UK is valsartan alone, meaning that the scope of that SPC does not encompass products containing valsartan and other active ingredient(s) which would require a further marketing authorisation.

The CJEU effectively decided that the scope of an SPC is not necessarily limited to just medicinal products containing, as active(s), only those ingredient(s) specified as being the "product" of the SPC.

This is because the CJEU held that SPCs granted for a "product" should confer the same rights as those conferred by the basic patent for that "product" in the form of a medicinal product. In other words, if a patent could have been used to oppose the marketing of a medicinal product containing a combination of active ingredients (eg A+B) then an SPC based upon that patent and directed to only one of those active ingredients (eg either A or B) can also be used to oppose the marketing of that combination product.

Although the court's ruling relates to a case in which the SPC is for a single active ingredient, the logic of the ruling should also hold true for SPCs to combinations of active ingredients. Thus, we expect that an SPC for A+B would be infringed by the sale of a medicinal product containing A+B+C, in the same way that an SPC for A would be infringed by the sale of a medicinal product containing A+B (and a medicinal product containing A+B+C).

A curious aspect of the CJEU's recent decisions is the different interpretations afforded to seemingly very similar wording from different articles of the SPC legislation. That is, the phrase "protected by a basic patent" in Article 3(a) is now interpreted very differently to the phrase "protection conferred by the basic patent" in Article 4 of the legislation.

For Article 4, the *Novartis v Actavis* decision makes it clear that "protection conferred by" an SPC can be understood in the classical infringement sense (albeit restricted to authorised medicinal products which contain the "product"). However, a striking aspect of the *Medeva* decision is that what is protected by a basic patent is not to be assessed in this way, but instead by a much more restrictive test based upon what is specified in the wording of the claims of the basic patent.

This distinction may appear bizarre to the uninitiated, but actually makes a great deal of sense for the practical application of the SPC legislation. This is because it helps strike an important balance between the need to ensure an appropriate reward (ie suitably broad protection) for innovative products that are new to the market and the need to prevent undue "evergreening" of protection.

Practical consequences

An SPC granted for active ingredient A may now be used to prevent a competitor from marketing any authorised product that contains A (eg A+B) after the basic patent's expiry and whilst the SPC is in force.

In the *Novartis v Actavis* case, this should mean that Actavis's arguments will fail. This is because Novartis's SPC to valsartan could have been used to oppose the launch of generic versions of not only Diovan but also Diovan HCT. However, the UK High Court has yet to issue its ruling on this point.

More broadly, it should mean that generic manufacturers will now need to delay launch of their versions of combination products until the time that, in the country of proposed launch, all SPC protection has expired (or has been invalidated) in respect of:

- each individual active ingredient present in the innovator product; and
- any (sub-)combination(s) of actives present in the innovator product for which SPCs may have also been obtained.

References

1. *Regulation 469/2009 (for human medicinal products) and Regulation 1610/96 (for plant protection products)*
2. *European court decisions on SPCs gives drug combinations more protection, Scrip Regulatory Affairs, 6 December 2011*
3. *Snodin, Miles and Pears, "Supplementary Protection Certificates: the CJEU issues its decision in two seminal cases", Bio-Science Law Review 12(2), 58-62*
4. *Order of the Court (Eighth Chamber), 9 February 2012, Case C 442/11, http://bit.ly/GEliFs*

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