Supplementary protection certificates: is a new era beckoning for combination drugs in the EU?

Michael Pears and *Mike Snodin* consider the opinion of an advocate general of the Court of Justice of the EU on granting supplementary protection certificates for combination medicines.

In a non-binding opinion issued on 13 July, Advocate General Verica Trstenjak of the Court of Justice of the European Union concluded that supplementary protection certificates should be granted to patented parts of medicinal products so as to meet the objectives of Regulation (EC) No 469/2009 on SPCs[1,2].

Professor Dr Trstenjak's opinion, which concerns two cases – *Medeva* and *Georgetown et al* – will now be considered by the CJEU when preparing its formal binding decision, the issue of which may well be delayed pending other cases at the CJEU that are considering similar issues. Although rulings of the CJEU often follow opinions of its advocates general, this is not always the case.

If the CJEU follows the opinion, it will harmonise divergent SPC practice across Europe for many medicinal products that comprise combinations of two or more active ingredients. More specifically, it might make it possible to obtain SPCs for a product that is defined as one or more (but not necessarily all) of the active ingredients of an authorised medicine or plant protection product containing multiple actives, provided that the product:

(a) constitutes the subject matter of a patent;
(b) has not formed part of a previously authorised medicine (or plant protection product); and
(c) has not been the subject of an earlier SPC.

This could lead to a new era in which combination products will be protected by a greater number of broader SPCs, in which the protection provided by those SPCs is more closely matched to the innovation in the patent(s) on which the SPCs are based.

On the other hand, the advocate general's view in relation to point (a) above could also, if followed by the CJEU, have the effect of invalidating a number of SPCs that have previously been granted on the premise that it is sufficient if the protective effect of a patent encompasses the product in question. Although it may not yet be clear what is meant by "the subject matter of a patent", it is certain that it will be interpreted to have a narrower scope than the protective effect of a patent (ie infringement).

Confusion over Articles 3(a) and 3(b)

The availability of an SPC is critically dependent on what the product is, this being defined as "the active ingredient or combination of active ingredients of a medicinal product".

Under Regulation (EC) No 469/2009, any product that is protected by a basic patent in force, and that is validly authorised for marketing as a medicinal product, is eligible for SPC protection, so long as it is new to the market and has not previously been protected by an SPC. However, in the context of SPC applications to products containing multiple active ingredients, a number of questions have arisen as to the precise circumstances in which a product is protected by a patent (under Article 3(a) of the regulation), and what constitutes "a valid authorisation" for the product (under Article 3(b) of the regulation).

For example, for a product defined as A+B, is it sufficient that the basic patent protects only A and that A+B infringes the patent, or must the patent somehow identify both A and B? Similarly, is an authorisation for A+B a valid authorisation of a product defined as A alone?

Medeva and Georgetown et al

The SPC applications of Medeva and Georgetown et al relate to vaccines containing multiple antigens, and bring these issues to the fore.

Medeva filed five SPC applications in the UK. Four of the applications define the product as a combination of antigens where some, but not all, are disclosed in the patent. The remaining application defines the product as containing some, but not all, of the antigens in the authorised vaccine. The four applications were refused by the UK Intellectual Property Office (and, on appeal, by the English High Court) for failing Article 3(a), it being held that basic patent did not protect products where not all of the antigens of the product were disclosed in the patent. The remaining application was refused for contravening Article 3(b), it being found that the authorised vaccine was not a valid authorisation for a product that contained some, but not all, of the vaccine's antigens.

Georgetown et al filed several SPC applications in which the product was a single antigen while the authorised vaccine was a combination of antigens. Again, the UKIPO held that an authorised combination of antigens was not a valid authorisation for one of those antigens. The applications were refused under Article 3(b).

Upon appeal of the refusals, the English courts sought clarification from the CJEU on how to interpret Articles 3(a) and 3(b). In *Medeva*, five questions on Article 3(a) and one question on Article 3(b) were referred. In *Georgetown et al,* one question on Article 3(b) was referred, identical to that in *Medeva*. The questions are pending before the CJEU as joined cases C-322/10 and C-422/10.

Professor Dr Trstenjak is of the opinion that a product is protected by a basic patent under Article 3(a) if it forms the subject matter of the basic patent, as governed by national law. In reaching this view, she distinguishes between the subject matter of a patent and the protective effect of that patent.

The advocate general believes that an authorised combination of active ingredients validly authorises the placing on the market of a single one of those ingredients or a sub-combination thereof, under Article 3(b). She applies a teleological interpretation of the SPC Regulation to arrive at this position, asserting that an otherwise literal interpretation goes against the objectives of the regulation by denying SPC protection for combination products that are only partially patented.

Professor Dr Trstenjak also comments on the scope of protection offered by SPCs, indicating that an SPC provides protection against unauthorised production and distribution of all subsequent medicinal products that are authorised before the expiry of the certificate and which contain the active ingredient or combination of actives that is the subject of the SPC, even if they contain further active ingredients.

A workable approach

Although the advocate general seems to be ruling out an infringement test to establish whether a product is protected by a basic patent under Article 3(a), the precise test to be used remains unclear. At least some form of disclosure of each active ingredient of a product appears to be necessary, but how specific this must be is not known.

What is clear from the opinion, however, is the proposal for SPCs to be obtained for a patented part of authorised products containing a combination of active ingredients. In reaching this conclusion, the advocate general has obviously recognised the importance of providing SPC protection for active ingredients that are first authorised in combination with other active ingredients.

If the CJEU follows the opinion, the narrow interpretation of what is protected by a basic patent may mean that some granted SPCs are

invalid. On the other hand, the more permissive interpretation of what represents a valid authorisation could provide new opportunities for obtaining useful (and very broad) SPC protection.

Overall, the above-mentioned aspects of the opinion provide what seems to be a workable approach for obtaining SPC protection for combination products.

While the facts of the *Medeva* and *Georgetown et al* cases relate to combination vaccines, the issues apply equally to other areas of human and veterinary medicine and also in agriculture. Indeed, an increasing trend to authorise medicines and plant protection products in combination suggests that the CJEU decision may have far-reaching consequences. The final judgement will therefore be eagerly anticipated.

References

1 *CJEU opinion Medeva and Georgetown et al v Comptroller-General of Patents (joined cases C 322/10 and C-422/10), 13 July 2011, http://bit.ly/rkOTuM*

2. *Messy compromise on combo SPCs in EU could increase thickets and litigation, Regulatory Affairs Pharma, 15 July 2011*

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