Opinion of Advocate General Trstenjak

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Last week, Advocate General Trstenjak gave her opinion on the latest supplementary protection certificates (SPC) case to reach the Court of Justice of the European Communities (CJEU). The case centred around whether a new medical use for a previously known pharmaceutical active ingredient can ever warrant a new SPC. The Advocate General's conclusions give hope for applicants of SPCs that 'second medical use patents' - now permitted by Article 54(5) EPC (implemented by EPC 2000) - may now warrant SPCs.

The facts of the case

Neurim applied for a supplementary protection certificate (SPC) for 'Circadin' - a medicinal product for the treatment of insomnia in humans, the active ingredient of which is melatonin. Melatonin had previously been authorised in an earlier veterinary product, 'Regulin' for the regulation of reproductive cycles in sheep.

Neurim's position was that to deny it an SPC on the basis of the earlier, but unrelated, marketing authorisation for 'Regulin' would contravene the objectives of the Regulation.

On Neurim's application, the UK Intellectual Property Office (IPO) relied primarily on three judgments of the CJEU, namely MIT, Yissum and Pharmacia. It argued that the position was 'acte clair' (i.e. clear from previous CJEU case law) and that Neurim's SPC should not be granted. It also argued that Neurim's application for an SPC should have been made on the basis of the earlier authorisation for 'Circadin'.

On first appeal to the UK Patents Court, Mr Justice Arnold agreed. However, the Court of Appeal later disagreed that the law was 'acte clair' and ordered a referral to the CJEU. In its judgment the Court of Appeal said "if Neurim are wrong, then the Regulation will not have achieved its key objects for large areas of pharmaceutical research"

In the questions referred, the UK Court of Appeal asked the CJEU whether article 3(d) precludes the grant of an SPC where an earlier marketing authorisation for a product not protected by the basic patent exists. The CJEU heard oral argument on 15 March 2012 at which Neurim, the UK Government, the Portugese Government and the Commission made representations.

The relevant provision of the SPC regulation is Article 3 of Council Regulation (EEC) No 1768/92 ("the SPC Regulation"), which states as follows:

"Conditions for obtaining a certificate.

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted, and at the date of that application:

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a. the product is protected by a basic patent in force;

b. a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;

c. the product has not already been the subject of a certificate;

d. the authorisation referred to in (b) is the first authorisation to place the product on the market as a medicinal product

**Highlights from the Advocate General's opinion**

**No definitive answer on this issue in previous case-law:**

The Advocate General acknowledged that "this question has not yet been answered definitively by the Court in its previous case-law". She considered both literal and teleological interpretations of the relevant articles (primarily article 3) of the SPC Regulation.

She noted that (as had been the case in the case-law mentioned above) "a purely literal interpretation of Article 3(d) of Regulation No 1768/92 would mean that, in a case like the main proceedings, no supplementary protection certificate can be granted for the medicinal product for human use Circadin. This follows directly from the combined operation of Article 1 and Article 3 of Regulation No 1768/92."

In her subsequent teleological assessment of the relevant article, she commented that Article 3(a) recognises three different types of patent - product patents, process patents and use patents. It is perfectly possible for the same active ingredient to be the subject of more than one patent at the same time. She said: "It must there be assumed that, in principle, Article 3(a) permits the grant of more than one supplementary protection certificate for a product. The same finding applies to article 3(b)".

Although article 3(c) states (on a literal interpretation) that only one SPC shall be granted per 'product', this article has been the subject of case-law which has decided that this restriction must in fact be interpreted "to the effect that only one certificate may be granted for each basic patent which protects an active ingredient".

She concluded: "A common feature of the conditions under Article 3(a), (b) and (c) of Regulation No 1768/92 is therefore that, in principle, they permit the grant of more than one supplementary protection certificate for a product. Against that background, the schematic context of Article 3(d) of Regulation No 1768/92 suggests an interpretation of that provision which essentially also permits the grant of more than one supplementary protection certificate for a product."

**The objectives of the SPC Regulation:**

The Advocate General considered the objectives of the SPC Regulation and the balance it sought to strike between research-based manufacturers and generic manufactures of pharmaceuticals on the one hand, and between the needs of patients and national health authorities on the other. She noted the importance of proceeding with great caution when making a teleological interpretation of the individual provisions of the Regulation.
She opined that the principal function of article 3(d) was to set time limits - both in relation to the time for applying for an SPC, and in relation to the duration of the SPC.

She concluded that "In this overall context, Article 3(d) of Regulation No 1768/92 does not, in my view, seek to preclude without exception the grant of a supplementary protection certificate based on an authorisation to place a product on the market ... where there is an earlier authorisation to place that product on the market as a medicinal product in that Member State. Furthermore, such an absolute preclusive effect of Article 3(d) would be not compatible with the objectives of Regulation No 1768/92."

**Examination of the facts:**

The Advocate General noted: "Neurim Pharmaceuticals developed a new medicinal product for human use, for which a patent was granted. This kind of pharmaceutical research, where new formulations and uses of known active ingredients are investigated, is an important part of research in the pharmaceutical sector. ... increasingly pharmaceutical research involves new formulations of old active substances."

She noted support for her interpretation in Article 54(5) EPC (which allows second medical use patents) and the Explanatory Memorandum to the SPC Regulation, saying: "These observations show that manufacturers of medicinal products which, as a result of their research, discover new therapeutic applications of active ingredients which are already used in authorised medicinal products and are also granted patent protection may have a legitimate interest in the extension of that exclusive protection by obtaining a supplementary protection certificate in order to cover the investment in research in accordance with the objective of Regulation".

In conclusion she said: "Article 3(d) must therefore also be interpreted to the effect that a supplementary protection certificate may be granted for a product protected by a basic patent in force only on the basis of the first valid marketing authorisation, in the Member State for which the application is made, for a veterinary medicinal product or a medicinal product for human use which contains that product and is within the scope of protection of that basic patent."

**Previous case law:**

She noted that there were two different lines of earlier case-law relating to SPCs arising from the CJEU. The first is the line taken in *Medeva et al*, in which a more purposeful construction of the legislation has been taken by the CJEU. This contrasted with the other line of cases (such as *Synthon* and *Generics (UK)*) in which she said: "The Court tends towards a stricter approach". She also said that her opinion in this case "can be classified in the first line of the Court's case-law".

**How should the CJEU answer the questions put to it?**

The Advocate General emphasised on several occasions that to obtain a new SPC: "The crucial factor ... is that the first use of an active ingredient which is authorised as a medicinal product is not within the scope of protection conferred by the patent which has been designated by the applicant as the basic patent for a further use of that active ingredient in another medicinal product."

In accordance with this principle, she proposed that the answers to the questions put to the CJEU should be that for the purposes of both article 3(d) (first marketing authorisation in the Member State)
and article 13(1) (first marketing authorisation in the Community), the relevant marketing authorisation is:

"The first authorisation which permits that product to be placed on the market as a medicinal product which is within the scope of protection conferred by the basic patent designated by the applicant."

This latest opinion from the Advocate General will be a welcome one for pharmaceutical patentees, and particularly those involved in research into new uses of old products.

It appears to be a sensible opinion which applies the purposes for which the SPC Regulation is stated to have been implemented and puts Europe more in line with Japan where patent term extensions have always been permitted for new uses of previously authorised active ingredients. As usual, however, with such cases relating to SPCs, the opinion has already led to much debate from commentators as to whether or not it reflects the best way forward. That debate appears to be split along research-based/generic lines, the former supporting the opinion and the latter suggesting it illegitimately re-writes the SPC regime. We must now await the judgement of the court to see if it follows the Advocate General's opinion.

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