J A • K E M P

BRIEFING

HIGH COURT REFERS SPC ISSUES TO THE CJEU

In two judgments handed down on 13 January 2017 Mr Justice Arnold decided to send questions on the SPC Regulation to the CJEU for a preliminary ruling. In each case the question reflects the lack of clarity provided by earlier key CJEU decisions, *Medeva*[1] and *Neurim*[2].

Article 3(a) is the product "protected by a basic patent in force".

In *Teva UK Limited and Others v Gilead Sciences Inc.*[3] at paragraph 95, Arnold J referred, not for the first time[4], the following open question:

> *What are the criteria for deciding whether 'the product is protected by a basic patent in force' in Article 3(a) of the SPC Regulation?*

The SPC was for a combination: tenofovir disoproxil (TD, present in the medicinal product as the fumarate salt TDF) and emtricabine (FTC). The patent claimed new compounds by formula including in particular (at Claim 25) TD. There was no claim or disclosure specific to FTC. Claim 27 was as follows:

[1] C-322/10 Medeva BV v Comptroller-General of Patents - View.
[2] C-130/11 Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents – our briefing on the decision is here.
[3] Teva UK Limited and others v Gilead Sciences Inc [2017] EWHC 13 (Pat) – View.
[4] Arnold J had previously referred the same question in Actavis v Sanofi, he did not get an answer. See also footnote 5.

> *A pharmaceutical composition comprising a compound according to any one of claims 1-25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients.*

The Judge had to consider whether the basic patent protected the combination given the case law of the CJEU, in particular *Medeva,* that an SPC could not be granted for an active ingredient or combination of active ingredients which was not specified in the wording of the claims.

In posing the question Arnold J proposed his own answer, which was that the Court should decide that to be protected by the basic patent for SPC purposes:

> *…the product must infringe because it contains an active ingredient or combination of active ingredients which embodies the inventive advance (or technical contribution) of the basic patent. Where the product is a combination of active ingredients, the combination, as distinct from one of them, must embody the inventive advance of the basic patent…*

Arnold J drew support for his proposed answer from the CJEU Judgments in C-443/12 *Actavis v Sanofi*[5] and C-577/13 *Actavis v Boehringer*[6].

Article 3(d) identification of the first authorisation to place the product on the market as a medicinal product.

In *Abraxis Bioscience LLC v The Comptroller-General of Patents*[7] Arnold J referred the following question:

> *Is Article 3(d) of the SPC Regulation to be interpreted as permitting the grant of an SPC where the marketing authorisation referred to in Article 3(b) is the first authorisation within the scope of the basic patent to place the product on the market as a medicinal product and where the product is a new formulation of an old active ingredient?*

The case concerned an SPC application for Nab-paclitaxel (nano-particle albumin bound paclitaxel). Having decided that Nab-paclitaxel was not a distinct active ingredient to paclitaxel, Arnold J had to consider whether the CJEU decision in

[5] C-443/12 Actavis v Sanofi concerned an SPC for irbesartan and hydrochlorothiazide, the Court drew a distinction, in the context of Article 3(c) between irbesartan, the core inventive advance, and other ingredients referred to in the claims in general terms.
[6] C-577/13 Actavis v Boerhinger the SPC was for telmisartan and hydrochlorothiazide, at paragraph 38 the Court stated *…for a basic patent to protect 'as such' an active ingredient…the active ingredient must constitute the subject-matter of the invention covered by the basic patent.*
[7] Abraxis Bioscience LLC v The Comptroller-General of Patents [2017] EWHC 14 (Pat) – View.

Neurim allowed for the grant of an SPC on the basis that Nab-paclitaxel was a new formulation of paclitaxel.

The question was, therefore: for the purposes of Article 3(d) was the relevant authorisation the first authorisation *within the scope of the basic patent* to place the product on the market as a medicinal product (here the first authorisation for Nab-paclitaxel). If no, that would mean that the Neurim decision must be interpreted as confined to new therapeutic uses of old active ingredients.

January 2017

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