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English Court of Appeal refers questions on the SPC Regulation

Brian Cordery (Bristows) · Tuesday, July 13th, 2010

Council Regulation 469/2009 (the "SPC Regulation") governs the grant of supplementary protection certificates in the EU. Core to its interpretation are Articles 1, 3, 4 and 5. Most pertinently, Article 3 provides that an SPC shall be granted if, among other things and in the relevant member state, (a) the product is protected by a basic patent in force, and (b) a valid authorisation to place the product on the market as a medicinal product has been granted. The "product" is defined as the active ingredient or combination of active ingredients of a medicinal product (Article 1(b)). The "basic patent" is defined as a patent which protects the "product" (Article 1c)).

In *Farmitalia Carlo Erba Srl's Supplementary Protection Certificate* (Case C-392/97) the ECJ considered whether the SPC Regulation requires an SPC to be restricted to the particular form of the active ingredient described in the medicinal authorisation. The Court held that it does not and that an SPC is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent. As regards the criteria for determining whether or not a product is protected by a basic patent, the Court's answer was that in the absence of Community harmonisation of patent law, the extent of patent protection can be determined only in the light of non-Community rules which governs patents.

(For the UK, section 125 of the Patents Act 1977 and the Protocol on the Interpretation of Article 69 of the EPC make clear that a product is protected by a patent if it falls within the scope of a claim).

The interpretation of the ECJ's guidance in *Farmitalia* has caused some difficulties in the English Courts. The first such case, *Takeda Chemical Industries Ltd's SPC Applications* (no. 3) [2004] RPC 3, was heard by Jacob J, who now sits in the Court of Appeal but at the time was a first instance Judge. As regards the interpretation of Article 3(a), he took the view that establishing the product would infringe the basic patent is not sufficient. The patent in question protected the compound lansoprazole but the marketing authorisation was for its use in combination with an antibiotic. Jacob J held that since only the lansoprazole element was protected by the patent, the "combination" was not "protected by a basic patent in force". The emerging principle was that the only ingredients which could be protected within the meaning of the SPC Regulation were the active ingredients of the product. However Jacob J. was not referred to *Farmitalia* in *Takeda* and so could not have taken it into account.

As regards Article 3(b), Jacob J. took the view that the marketing authorisations for lansoprazole for use in the various indications were not "a valid authorisation to place the product on the market as a medicinal product". This was because the licences did not permit the marketing of the antibiotic component – that would have its own marketing authorisation.

Subsequent cases: *Gilead Sciences Ltd's SPC Application* [2008] EWHC 1902 and *Astellas Pharma Inc v Comptroller General of Patents* [2009] EWHC 1916 developed and applied but doubted the *Takeda* reasoning as the "clear pointer" test (Article 3(a)) and noted uncertainty as to the application of the *Farmitalia* judgment. In *Gilead*, Kitchin J. found that a claim for "A plus optionally any other therapeutic agent" protected A plus B even though B was not itself mentioned expressly. In *Astellas*, Arnold J. expressed the view that the decision as to whether to refer to the ECJ for clarification of its judgment in *Farmitalia* was one that should be made by the Court of Appeal.

Courts within the EU seem to be split as to which is the correct approach. For example, the infringement test seems to have been adopted by the Federal Supreme Court of Germany (Case X ZB 12/00 of March 2002), but an approach akin to the "clear pointer"/*Takeda* approach appears to have been taken in Sweden (*AB Hässle*).

The Court of Appeal has now been asked to consider similar questions in *Re Medeva's SPC Applications* [2010] EWCA Civ 700. The questions are: first, whether a patent covering the combination of A plus B (in a vaccine) protects, for the purposes of the SPC Regulation, a vaccine comprising A plus B, C, D and E (Article 3(a)); and second, whether the marketing authorisation for the full A-E combination is to place on the market the SPC "product", when it is defined simply as A plus B (and which the patent therefore must protect) (Article 3(b)). Medeva submits that to the extent it is unlikely to be granted an SPC on the basis of the latter (the "A plus B" SPC product definition), this supports its case in relation to the former (for which the SPC "product" is the A-E combination).

The Court of Appeal have decided to refer a number of questions to the ECJ, which they have summarised as follows:

(1) What is the test by which to determine whether "the product is protected by a basic patent in force" for the purposes of Article 3(a)?
(2) Should a different test be applied in cases where the product is a multi-disease vaccine?
(3) Is it sufficient for the purposes of Article 3(a), in the context of a multi-disease vaccine, that the basic patent in force protects one aspect of the product?
(4) For the purposes of Article 3(b) may the product be limited to that part of a multi-disease vaccine as is protected by the basic patent in force.

Assuming a normal timetable, the CJEU might be expected to deliver its judgment towards the end of the first half of 2012.

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