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SPC Regulation: Does “protected by the basic patent” mean claimed as such in the basic patent?

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The protected product within the meaning of Article 3 (a) of SPC Regulation (EEC) No. 1768/92 must be a product claimed as such in the basic patent.

Daiichi Sankyo Company Limited (Daiichi) owns a European patent covering anti-hypertensive compounds, a family of 1-biphenylimidazole derivatives, among which olmesartan medoxomil, their pharmaceutically acceptable salts and esters, as well as their preparation and their therapeutic use.

Daiichi applied for a supplementary protection certificate (SPC) for a proprietary medicine containing olmesartan medoxomil and hydrochlorothiazide (a diuretic which by eliminating part of the water and sodium contained in blood contributes also, by decreasing blood volume, to lowering blood pressure level) as active ingredients. By way of a decision of 3 December 2008, the Director General of the French patent office, the *Institut National de la Propriété Industrielle*, rejected the application.

Daiichi lodged an appeal against that decision before the *Cour d’Appel* of Paris. In its decision of 6 November 2009, the Court dismissed the appeal on the grounds that according to the conditions for obtaining a certificate listed in Article 3 of Regulation (EEC) No. 1768/92 of 18 June 1992 (replaced in the meantime by Regulation (EC) No. 469/2009 of 6 May 2009) the product must be both “protected by a basic patent in force” and the subject of “a valid authorisation to place the product on the market as a medicinal product”.

The Court then noted that the marketing authorization (MA), in this case, was obtained for a proprietary medicine combining two active ingredients, olmesartan medoxomil and hydrochlorothiazide, of which the first, not the second, belongs to the family of 1-biphenylimidazole derivatives covered by the claimed basic patent. Considering that the product concerned by the MA, a combination of olmesartan and hydrochlorothiazide, is not the product protected by the basic patent (olmersartan), the Court decided that the condition of Article 3 (a) of Regulation (EEC) No. 1768/92 was not met.

It affirmed the decision of the Director General of the *Institut National de la Propriété Industrielle* to reject the application.

This decision of the *Cour d’Appel* of Paris thus confirms a series of French cases in which it was

decided that the protected product within the meaning of Article 3 (a) of Regulation (EEC) No. 1768/92 must be a product claimed as such in the basic patent (see *CA* Paris, 4th ch., sect. A, 19 January 2005, Docket No. 2004/14435, PIBD 2005, No. 809, III, 333; *CA* Paris, 4th ch., sect. B, 9 December 2005, Docket No. 2005/11874; *CA* Paris, 4th ch., sect. A, 8 February 2006, Docket No. 2005/20525, PIBD 2006, No. 828, III, 275; *CA* Paris, 4th ch., sect. A, 9 April 2008, Docket No. 2007/15741, PIBD 2008, No. 877, III, 389).

However, one may wonder if such a solution is in accordance with the ECJ's ruling in *Farmitalia* (C-392/97). ECJ made a link between Article 3(a) (the product is protected by a basic patent in force) and Articles 4 and 5 of the Regulation No. 1768/92 (concerning only the product covered by the MA, the certificate shall have exactly the same scope of protection as the basic patent), deciding that, in order to determine, in connection with Article 3(a), whether a product is protected by a basic patent, reference must be made to the non-Community rules which govern that patent and determine its scope of protection. Yet, it is settled case law, in the field of patents, that patent infringement is established (i.e. the patent confers protection) when the patented element can be found as such among other elements in the same litigious object. Thus, it would be possible to say that the basic patent covering olmesartan protects the product containing both olmesartan and hydrochlorothiazide.

Original French decision.
English translation .

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