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SPCs and Combination Products

Eike Schaper · Friday, July 22nd, 2011 · Landmark European Patent Cases

Combination products (containing two or more active ingredients) raise difficult questions with respect to supplementary protection certificates (SPCs).
Can a SPC be based on the market authorisation (MA) of a combination product, if the patent only covers one active ingredient?
On 13 July 2011, the Advocate General at the CJEU delivered her Opinion on the interpretation of Article 3(a) and 3(b) of the SPC Regulation (EC) No 469/2009 in two joint cases – both reference for a preliminary ruling from a UK court (C?322/10 – Medeva BV v Comptroller-General of Patents, Designs and Trade Marks; and C?422/10 – Georgetown University, University of Rochester, Loyola University of Chicago v Comptroller-General of Patents, Designs and Trade Marks).
Based on a teleological interpretation, the Advocate General came to the conclusion that the Regulation is also intended to cover medicinal products in which the combination of active ingredients is not patented in its entirety but nevertheless includes a patented active ingredient or combination of active ingredients. A valid MA within the meaning of Article 3(b) of the SPC Regulation may also exist where that authorisation relates to a medicinal product which also contains, together with the patented active ingredient or combination of active ingredients, one or more other active ingredients (Opinion, points 118 and 119).
The judgement of the CJEU is eagerly awaited; not only by the English courts, which referred in 2010 five cases to the CJEU regarding the interpretation of the SPC Regulation (cf. the post by Bristows), and by the French courts, which have stayed the proceedings relating to SPCs until the CJEU has handed down its decision (cf. the post by Véron).

Another question which has been litigated in several European countries (inter alia in Belgium, France, Germany and Norway) is the question whether a combination product (containing two or more active ingredients) falls under the scope of a SPC for one of these active ingredients (mono SPC).
In Germany, the Düsseldorf District Court decided that the distribution of a generic which combines two active ingredients – valsartan and hydrochlorothiazide (HCTZ) – infringes the SPC granted for the active ingredient valsartan (Novartis v Actavis, judgement of 8 March 2011, 4b O 280/10). In coming to this conclusion, the court has discussed the interpretation of Articles 4 and 5 SPC Regulation in depth. Although it considers a SPC not merely as a prolongation of the term of a patent, but as a property right sui generis, it still considers the general principles of patent law to be applicable: “According to principles of patent law, which, pursuant to Articles 4 and 5 SPC Regulation, likewise apply to the SPC in suit, it is irrelevant for the issue of an infringement whether or not a medicinal product, apart from the active ingredient valsartan, additionally shows

further features; in particular, an infringement cannot be denied in case a medicinal product contains one or more other active ingredients in addition to valsartan."
The opinion delivered by the Advocate General on 13 July 2011 in a different context, confirms that a mono SPC covers combination products:
"In so far as the basic patent for the certificate-protected active ingredient …offers the patent proprietor protection against unauthorised production and distribution of medicinal products containing that active ingredient …, the SPC for that active ingredient … therefore also gives protection against unauthorised production and distribution of all subsequent medicinal products which are authorised before the expiry of the certificate and contain that active ingredient" (Opinion, point 108; cf. point 123).

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