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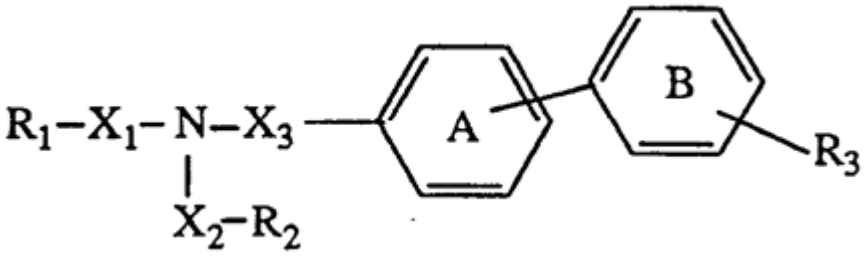
SPC – Novartis v Actavis (valsartan): the sequel

Pierre Véron (Véron & Associés) · Monday, November 21st, 2011

As already explained in a previous post, the company governed by the laws of Switzerland, Novartis AG, is the holder of patent EP 0 443 983 entitled "*Acyl compounds*", whose subject-matter is a group of antihypertensive compounds, including valsartan, pharmaceutical preparations containing them and processes for the preparation of these compounds.



This patent, filed on 12 February 1991, was to have expired on 12 February 2011. However, Novartis AG endeavoured to extend that protection by obtaining the grant of the supplementary protection certificate (SPC) No. 97 C 0050. This SPC should normally expire on 13 May 2011 but its validity was extended until 13 November 2011, through a "paediatric extension".

The company governed by the laws of France, Novartis Pharma, was the holder of an exclusive licence under the French designation of patent EP 0 443 983 and of an exclusive licence under SPC No. 97 C 0050. It markets in France two pharmaceutical products containing valsartan, for which it is the holder of different MAs, under the TAREG and COTAREG trademarks. TAREG is indicated for the treatment of high blood pressure, heart failure and post-myocardial infarction. COTAREG is a medicinal product for human use, which combines two active ingredients, valsartan and a diuretic, hydrochlorothiazide "HCTZ", and which is indicated for the treatment of high blood pressure.

The company governed by the laws of Iceland, Actavis Group PTC EHF, obtained in France, on 30 November 2009, the grant of MAs for pharmaceutical products which challenge COTAREG: "valsartan hydrochlorothiazide Actavis 80mg/12.5mg" and "valsartan hydrochlorothiazide Actavis 160mg/25mg". It designated Actavis France as the exploiting company of these marketing authorisations.

The Novartis companies, after having advised the Actavis companies of the existence of their SPC rights until 13 May 2011 and until 13 November 2011 because of the paediatric extension, served a summons dated 11 January 2011 on the Actavis companies to a preliminary hearing at set times.

Pursuant to Article L. 615-3 of the French Intellectual Property Code, which implements Article 9 of Directive 2004/48/EC and notably makes it possible to request an interlocutory injunction intended to "prevent any imminent infringement" of patents and related rights (SPC), the Novartis companies asserted the "threat of an imminent infringement" of their rights (patent EP 0 443 983 and SPC No. 97 C 0050) on the grounds of steps made in France to market, as of May 2011, the pharmaceutical products including valsartan, for which the defendants obtained MAs and a reimbursement rate by the *CEPS*. According to the claimants, the French designation of patent EP 0 443 983 and the SPC No. 97 C 0050, covering valsartan, could be asserted against any product containing valsartan, including a product containing valsartan and another product as a diuretic such as hydrochlorothiazide. On that basis, they requested that the Judge enjoin the defendants, under penalty, from manufacturing, importing, marketing, using and holding pharmaceutical preparations implementing the features covered by patent EP 0 443 983 and SPC No. 97 C 0050.

In its order handed down on 28 January 2011, the Presiding Judge of the *Tribunal de Grande Instance* of Paris ordered the interlocutory injunction requested by Novartis. Its analysis was based on Articles 4 and 5 of Regulation No. 469/2009. In its opinion, Article 4 can be read as follows: "*Within the limits of the protection conferred by the basic patent [patent EP 0 443 983], the protection conferred by a certificate [SPC No. 97 C 0050] shall extend only to the active ingredient [i.e. valsartan] covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate*". With the subject-matter of the protection of the SPC having been so precisely delimited pursuant to Article 4 of Regulation No. 469/2009, the Judge then applied Article 5 of the same regulation to underline the fact that the SPC confers on its subject-matter "*the same rights as conferred by the basic patent*". Consequently, the Novartis companies, enjoying the same rights as conferred by the basic patent, "*can oppose any use of this active ingredient for treating high blood pressure, alone or in combination with another active ingredient*".

The Actavis companies then lodged an appeal. And in its 16 September 2011 decision, the *Cour d'Appel* of Paris (Division 1, Chamber 4) reverses the order and dismisses the requests for injunctions. The *Cour d'Appel* follows the opinion of the Actavis companies according to which the Presiding Judge mistook the notion of "product" for that of "active ingredient". Taking up the definitions given by the regulation in its Article 1, the *Cour d'Appel* of Paris underlines that the subject-matter of the protection conferred by the certificate is the "product". And the "product" as defined by the regulation is "*the active ingredient or combination of active ingredients of a medicinal product*". Therefore, the notion of "product" is distinct from the notion of "active ingredient" since the product may be a combination of active ingredients. And if the sole valsartan product is the subject-matter of the protection conferred by the certificate, the combination of valsartan with another active ingredient, such as hydrochlorothiazide (HCTZ), is another product, composed of a combination of active ingredients, which is not covered by the protection conferred by the certificate.

In other words, according to the *Cour d'Appel* of Paris, by defining the subject-matter of the protection conferred by the SPC, Article 4 defines two different things, not only the object that the holder of the SPC appropriates (the valsartan product which, in the present case, is a sole active ingredient) but also the object against which the holder of the certificate may assert the rights conferred by the SPC (he may assert his rights against any other person who manufactures or markets, without his authorisation, the product subject-matter of the SPC, the sole valsartan) and,

consequently, all the other objects against which the holder of the SPC has no right to assert (all products which do not only contain valsartan are not affected by the SPC holder's rights; *e.g.* the combination of valsartan and HCTZ is another "product" against which the SPC holder has no right to assert).

However, reading the reasoning of the *Cour d'Appel*, we may wonder if, under cover of defining the subject-matter of the protection conferred by the SPC, the *Cour d'Appel* is not actually imperceptibly switching to the definition of the effects of the certificate against third parties, which is a totally different question ruled by Article 5 (which refers to patent law) of the regulation and not Article 4.

We can only agree with the *Cour d'Appel* that the subject-matter of the certificate, the object appropriated by the SPC holder, is rather the product than the active ingredient since the product may be a combination of active ingredients. And, effectively, it allows to consider that the subject-matter of the protection conferred by the SPC, and reserved to Novartis, is the sole valsartan product. But to deduce again from Article 4 ("*Subject-matter of the protection*") the object manufactured and placed on the market by third parties against which the holder may assert the rights conferred by the SPC (the sole valsartan product) and the other objects manufactured and placed on the market by third parties against which the holder may not assert his rights (valsartan in combination with another active ingredient), is it not switching from the subject-matter of the protection to the effects of the protection which are ruled by Article 5 ("*Effects of the certificate*")?

We should precisely note that such a distinction between the subject-matter of the certificate and the effects of the certificate was drawn by the Presiding Judge in its order, first considering Article 4 to determine the subject-matter of the protection, the object appropriated by the SPC holder, and then moving to Article 5 to determine the effects of the SPC, the third parties' products against which the SPC holder may assert his rights: *i.e.*, according to patent law (referred to in Article 5), all products containing valsartan, alone or in combination with another active ingredient, as long as this combination does not deprive valsartan of its specific pharmaceutical activity.

However, we should remain very careful since this question is much debated not only in France but also abroad, a question having even been referred to the CJEU by the High Court of Justice for a preliminary ruling on the interpretation of Articles 4 and 5 of Regulation No. 469/2009 (reference for a preliminary ruling from High Court of Justice (Chancery Division) (United Kingdom) made on 26 August 2011 (C-442/11 – Novartis AG v Actavis UK Ltd)).

In France:

The *Cour d'Appel* of Paris is even divided on this question. In another case, relating to losartan but exactly similar to the present valsartan's case, another Chamber of the *Cour d'Appel* of Paris, on 15 March 2011, took an opposite position. In this case, Du Pont de Nemours (holder of the basic patent and of the SPC) and Merck (licensee), on the basis of a SPC which subject-matter was the losartan alone, had requested and obtained from the Presiding Judge of the *Tribunal de Grande Instance* of Paris (the same Presiding Judge as in the present valsartan's case between Novartis and Actavis), in an 12 February 2010 order, preliminary injunctions against the Mylan and Qualimed companies which were about to place on the French market a product combining losartan with another active ingredient, the hydrochlorothiazide (HCTZ, as in the present valsartan's case). The Chamber 3, Division 1 of the *Cour d'Appel* of Paris, on 15 March 2011, has affirmed the order on

the basis of a combined reading of Articles 4 and 5 of the regulation, such as described above.

Still about valsartan but in a litigation between Novartis and Sanofi-Aventis France, Sanofi Winthrop Industries and Zentiva KS (which also placed on the French market a combination of valsartan and HCTZ), the Presiding Judge of the *Tribunal de Grande Instance* of Paris in an 27 October 2011 order granted the preliminary injunctions requested by Novartis. Its reasoning is again based on a combined reading of Articles 4 and 5 of the regulation. And on 31 October 2011, the same judge refused to withdraw its 27 October 2011 order, even with full knowledge of the reference for a preliminary ruling from High Court of Justice (Chancery Division) made on 26 August 2011 (case C-442/11).

Abroad:

Novartis and Actavis develop parallel litigations in other countries, as we shall see in many posts. And in these parallel procedures, Novartis was rather successful.

In Norway, ruling on the merits, the District Court of Oslo decided on 10 February 2011 that the SPC covering valsartan also protects against valsartan in combination products.

In Austria, on 7 October 2011, the commercial court (*Handelsgericht*) of Vienna also gave satisfaction to Novartis, deciding on the basis of a combined reading of Articles 4 and 5 of the regulation and refusing to stay the proceedings in spite of the reference for preliminary ruling made by the High Court of Justice (C-442/11).

In Germany, Novartis obtained preliminary injunctions and, in the action on the merits, the question of the interpretation of Articles 4 and 5 of the regulation has again been referred for preliminary ruling to the CJEU by a 8 November 2011 decision of the District Court of Dusseldorf.

However, in Belgium, Du Pont de Nemours and Merck, in their similar case relating to losartan, had not such a chance in first instance (on 12 February 2010) and appeal (on 23 February 2010).

Therefore, the intervention of the CJEU seems more than necessary.

Original French decision, Novartis v Actavis.
English translation.

Original French decision, Novartis v Sanofi.
English translation.

Original French decision, CA Mylan, Qualimed v Du Pont de Nemours, Merck.
English translation.

Original French decision, TGI Mylan, Qualimed v Du Pont de Nemours, Merck.
English translation.

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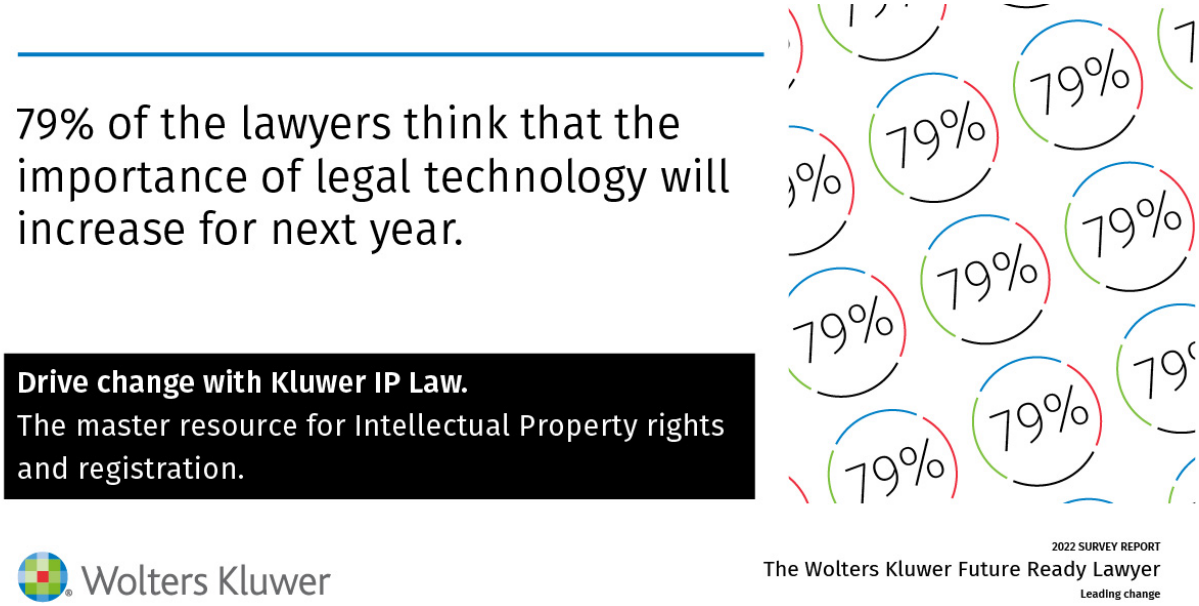

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