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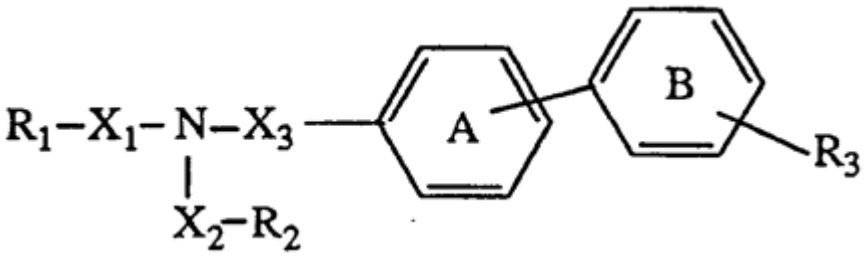
A poor consolation

Pierre Véron (Véron & Associés) · Wednesday, February 27th, 2013

On 15 January 2013, the French *Cour de cassation*, in the litigation between the Novartis companies and the Actavis companies about valsartan, drew the consequences of the 9 February 2012 order rendered by the CJEU in the frame of a parallel litigation in the United Kingdom.

As already explained in a previous post, the company governed by the laws of Switzerland, Novartis AG, was granted European patent EP 0 443 983 relating to "*acyl compounds*", including valsartan, and, after its expiry, a supplementary protection certificate (SPC) No. 97C0050 which was in turn the subject of a pediatric extension expiring on 13 November 2011.



The company governed by the laws of France, Novartis Pharma, was the holder of an exclusive licence for the patent and the SPC and also of several marketing authorizations (MA) for proprietary drugs containing valsartan marketed under the name Tareg or Cotareg. 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 80 mg/12.5 mg*" and "*valsartan hydrochlorothiazide Actavis 160 mg/25 mg*". 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. 97C0050) 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. 97C0050, 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. 97C0050.

In its order handed down on 28 January 2011, the Presiding Judge of the *tribunal de grande instance de 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. 97C0050] *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 de 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 de 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 de 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, through such a reasoning, the *cour d'appel*, under cover of defining the subject-matter of the protection conferred by the SPC, was 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. That's what the CJEU makes definitely clear in its 9 February 2012 order (CJEU, 8th ch., 9 February 2012, C-442/11, Novartis AG v. Actavis UK Ltd).

On 26 August 2011, the High Court of Justice (Chancery Division), to which the parallel proceedings between Novartis AG and Actavis UK Ltd was submitted, had referred the following question to the CJEU for a preliminary ruling concerning the interpretation of Articles 4 and 5 of Regulation No. 469/2009:

'*Where a supplementary protection certificate has been granted for a product as defined by Regulation No. 469/2009 for an active ingredient, are the rights conferred by that certificate pursuant to Article 5 of the Regulation in respect of the subject matter as defined in Article 4 of the Regulation infringed:*

(a) by a medicinal product that contains that active ingredient (in this case valsartan) in combination with one or more other active ingredients (in this case hydrochlorothiazide); or

(b) only by a medicinal product that contains that active ingredient (in this case valsartan) as the sole active ingredient? '

In its 9 February 2012 order, the CJEU ruled:

"*Articles 4 and 5 of Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, where a 'product' consisting of an active ingredient was protected by a basic patent and the holder of that patent was able to rely on the protection conferred by that patent for that 'product' in order to oppose the marketing of a medicinal product containing that active ingredient in combination with one or more other active ingredients, a supplementary protection certificate granted for that 'product' enables its holder, after the basic patent has expired, to oppose the marketing by a third party of a medicinal product containing that product for a use of the 'product', as a medicinal product, which was authorised before that certificate expired*".

This interpretation of Articles 4 and 5 of Regulation No. 469/2009 is now adopted by the French *Cour de cassation* in its 15 January 2013 decision. The Novartis companies have lodged before the *Cour de cassation* an appeal against the 16 September 2011 decision of the *cour d'appel de Paris*.

In its 15 January 2013 decision, the *Cour de cassation* first reminds that the *cour d'appel*, in order to reject Novartis' requests, maintained that the accused generic drug, comprising valsartan associated with HCTZ, did not constitute the same product as valsartan, which alone was covered by SPC No. 97C0050, and that therefore it was not realistic that any marketing of medicinal products containing valsartan as an active ingredient constituted infringement and violated the rights to this active ingredient held by Novartis.

And it then quashes the *cour d'appel* decision considering that "*in reaching this decision without ascertaining whether or not the rights held by Novartis regarding their patent No. EP 0 443 983 allowed them to oppose the use of valsartan as a medicinal product in the accused generic drugs associating it with HCTZ, and whether or not, consequently, the latter infringed SPC No. 97 C 0050, which, like the basic patent, related to valsartan and conferred identical rights as the said patent on Novartis, the* cour d'appel *provided no legal grounds for its decision*".

Therefore, at last, Novartis gets satisfaction, at least from a theoretical point of view. Its argument and interpretation of Articles 4 and 5 of Regulation No. 469/2009 were correct. The marketing of drugs associating valsartan and HCTZ may be an infringement of the SPC whose subject-matter was the sole valsartan. Novartis contributed to a better understanding of Articles 4 and 5 of Regulation No. 469/2009. But this *Cour de cassation* decision is only a poor consolation from a practical point of view. On the basis of its SPC and of Article L. 615-3 IPC, Novartis was requesting an interim injunction against the marketing of the Actavis drugs until the expiry of the SPC and that interim injunction request was dismissed by the decision now quashed. The proceedings was too long, the SPC expired on 13 November 2011, and even if the *Cour de cassation* approves today the argument of Novartis and its interpretation of Articles 4 and 5 of Regulation No. 469/2009, it is no more possible today to render such an interim injunction order. Article L. 615-3 IPC is clear. It allows "*any measure aimed at preventing an infringement about to be committed against rights conferred by the title or aimed at stopping any further allegedly infringing act*". It can no longer function once the SPC has expired. Therefore, the *Cour de cassation* states that the appeal, relating to the provisional measures which expired on 13 November 2011, is now useless, devoid of subject-matter so that it will not be referred back to a new *cour d'appel*.

Original French decision.
English translation .
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