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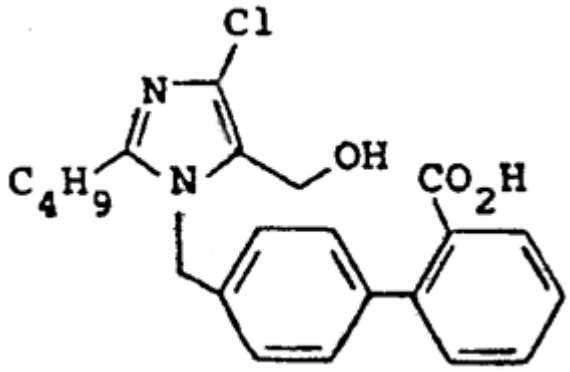
Losartan: SPC's paediatric extension and preliminary injunction

Pierre Véron (Véron & Associés) · Wednesday, August 29th, 2012

On 8 June 2012, the *Tribunal de Grande Instance* of Paris rendered an interesting decision concerning Losartan. It particularly deals with two questions: the conditions of the SPC's paediatric extension (Regulation (EC) No. 1901/2006) and the preliminary injunction as organized by Article L. 615-3 (implementing Article 9 of Directive (EC) No. 2004/48) of the French Intellectual Property Code.



The US company E.I. Du Pont de Nemours & Company (hereinafter referred to as "Du Pont de Nemours") was the holder of European patent EP 0 253 310 entitled *Angiotensin II receptor blocking imidazoles*, covering a group of antihypertensive compounds, including Losartan, until its expiry on 9 July 2007.

On the basis of this European patent, it was also the holder of SPC No. 95C0018, which also covered Losartan, extended by a "*paediatric extension*" resulting in the SPC's ensuing expiry on 2 March 2010.

The French company Laboratoires Merck Sharp & Dohme-Chibret (hereinafter referred to as "Merck") was the exclusive licensee of the French designation of the said patent and SPC, the holder of the marketing authorisation for the pharmaceutical drugs containing Losartan which it markets in France.

Having discovered in January 2010 that Mylan and Qualimed were about to market pharmaceutical drugs containing Losartan and hydrochlorothiazide, Du Pont de Nemours and Merck brought preliminary proceedings against them by way of a summons dated 2 February 2010, on the basis of

Article L. 615-3 of the French Intellectual Property Code. This article, implementing Article 9 of the Enforcement Directive No. 2004/48, provides that any person with authority to bring an action for infringement may request that the Judge ruling in preliminary proceedings order any measure aimed at preventing an imminent infringement of its rights or aimed at putting a stop on allegedly infringing acts. The provisional measures of Article L. 615-3 may be directed against an infringement (already) being committed but also against an infringement not yet committed but "*imminent*". In the present case, the alleged infringement was only "*imminent*", about to be committed but not yet committed.

Article L. 615-3 paragraphs 1 and 5
of the French Intellectual Property Code:
"*Any person with authority to bring an action for infringement may, in preliminary proceedings, request the competent civil court to order, under a penalty of a daily fine if necessary, against the alleged infringer or intermediaries whose services it uses, 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.* […]
When the measures taken to stop the infringement of rights are ordered before the commencement of proceedings on the merits, the claimant shall institute legal proceedings, either by civil action or criminal action, within a period of time set by regulation. Failing that, upon the defendant's request and without its having to justify its application, the measures ordered are void, without prejudice to the damages which may be claimed".

In an order dated 12 February 2010, the Presiding Judge of the *Tribunal de Grande Instance* of Paris enjoined, under penalty, Mylan and Qualimed "*from offering to sell and selling, that is, from marketing pharmaceutical compositions and in particular Losartan HCTZ Mylan 50 mg and 100 mg reproducing the characteristics covered in particular by claims 1, 2, 3, 4 and 5 of European patent No. 0 253 310 and SPC No. 95C0018, before 2 March 2010, under a €100 penalty per tablet offered for sale and sold in bulk or in any other packaging form, as of the date of service of the order*" (it may be noted that an appeal against this order was lodged by Mylan and Qualimed before the *Cour d'Appel* of Paris which, on 15 March 2011, affirmed the challenged order but held that the penalty need not be ordered, and that an appeal on a point of law was lodged before the *Cour de Cassation* against this last decision; in the present decision, the *Tribunal de Grande Instance* of Paris dismisses Mylan and Qualimed's request for a stay of proceedings pending the decision of the *Cour de Cassation*). This preliminary injunction was only effective until 2 March 2010, the date upon which the validity of SPC No. 95C0018, extended by a paediatric extension, ended.

Du Pont de Nemours and Merck then thought that they should be concerned by paragraph 5 of Article L. 615-3 which provides that, upon the defendant's request and without its having to justify its application, the provisional measures ordered are void if the claimant has not instituted legal proceedings, that is, initiated an action on the merits within a period not exceeding 20 working days or 31 calendar days, whichever is the longest, from the date of the order (Art. R. 615-1). The action on the merits referred to in this text is typically the infringement action aimed at obtaining damages and a permanent injunction. But in the case of Du Pont de Nemours and Merck where the provisional measure was aiming at preventing an imminent infringement and was effective so that no act of infringement was committed by the defendants (Mylan and Qualimed), the institution of an infringement action was, by definition, impossible. Was it then possible to avoid the nullity provided by paragraph 5 of Article L. 615-3? Du Pont de Nemours and Merck decided to bring

proceedings against Mylan and Qualimed, by way of summonses of 11 March 2010 (*i.e.* within the time period of 31 calendar days from the date of the order, pursuant to Article R. 615-1), before the *Tribunal de Grande Instance* of Paris in order to "*validate*" the 12 February 2010 order: "*In this context, in particular to comply with the time limit referred to in Article L. 615-3 of the French Intellectual Property Code, by way of summonses of 11 March 2010, Du Pont de Nemours and Merck brought proceedings against Mylan and Qualimed before the Tribunal de Grande Instance of Paris for the validation of the 12 February 2010 order and to order Mylan and Qualimed to pay them the sum of €30,000 pursuant to Article 700 of the French Code of Civil Procedure*".

However, the interpretation of Article L. 615-3, paragraph 5, on which Du Pont de Nemours and Merck were relying, may be challenged. The very beginning of paragraph 5 provides: "*When the measures taken to stop the infringement of rights are ordered* (…)". This text clearly only applies when the provisional measure was taken to stop an infringement already committed. And it does not apply when the provisional measure was taken to prevent an "*imminent*" infringement, about to be committed. The present case is even a good explanation of the scope of application of paragraph 5: if the infringement is only imminent and the provisional measure effective, the claimant should not find any opportunity to "*institute legal proceedings*" as required by Article L. 615-3, paragraph 5.

The action of Du Pont de Nemours and Merck, as it was aimed at the "*validation*" of the provisional measure ordered on 12 February 2010 had probably no legal basis and should have been held inadmissible for lack of interest. The defendants could not justify an interest in the action for "*validation*" of the provisional measure which was absolutely not threatened by the nullity provided by Article L. 615-3, paragraph 5. However, as for a plea of non-admissibility based upon lack of interest, the French judge is not compelled to raise it *sua sponte* (Art. 125 French Code of Civil Procedure). The *Tribunal de Grande Instance* of Paris, in its 8 June 2012 decision, did not intend to raise *sua sponte* a plea of non-admissibility and preferred to rule on the merits of the action of Du Pont de Nemours and Merck, noting that Article L. 615-3 did not empower the court to "*validate*" the order as requested: "*it does not result from the provisions laid down in Article L. 615-3 of the French Intellectual Property Code that the Judge ruling on the merits, to whom the case was referred pursuant to this Article after provisional measures were ordered in preliminary proceedings, has jurisdiction to validate* (…)*these measures*".

In their latest pleading, Du Pont de Nemours and Merck had also requested that the *Tribunal de Grande Instance* of Paris hold that the preliminary injunction, limited by the Presiding Judge of the *Tribunal* to the marketing of the products, should have applied to the acts of manufacturing, importing, using and holding for such purposes any drug containing Losartan. Article L. 613-3 expressly prohibits "*making, offering, putting on the market, or using a product which is the subject matter of the patent, or importing or stocking a product*".

However, the preliminary injunction ordered on 12 February 2010 was effective until 2 March 2010, the date of expiry of the extended SPC. Which interest could justify the claimants' request on 11 March 2010? The provisional measure had been ineffective since 2 March 2010 and it was practically no longer possible to go back on the fact definitively established that the preliminary injunction, from 12 February 2010 to 2 March 2010, had hindered the defendants only from marketing the products containing Losartan. Here again, a lack of interest was possible.

The *Tribunal de Grande Instance* of Paris notes that pursuant to Article L. 615-3 the Judge ruling on the merits has no jurisdiction to amend the ordered provisional measures, "*all the more since*

they are no longer relevant in this case".

The requests of the claimants, Du Pont de Nemours and Merck, being thus dismissed, the claims of the defendants, Mylan and Qualimed, still remained to be examined. The legal proceedings instituted on 11 March 2010 by Du Pont de Nemours and Merck and the legal proceedings instituted on 2 March 2010 by Mylan and Qualimed for the invalidity of the SPC extension, had been consolidated by order of 22 September 2011. In their latest pleading, Mylan and Qualimed challenged the validity of the extension granted to SPC No. 95C0018 and claimed that the combination of Losartan and HCTZ would be different from Losartan alone.

In order to challenge the validity of the paediatric extension granted to SPC No. 95C0018, Mylan and Qualimed argued, firstly, that this extension was subject to the grant of the marketing authorisation for a specific paediatric use for the product in the 27 Member States of the European Union and, secondly, that these authorisations had to be obtained at the time of filing the application for an extension and not after.

The *Tribunal de Grande Instance* of Paris dismisses these two arguments.

Regulation No. 1901/2006 on medicinal products for paediatric use does not require that the product has obtained marketing authorisations only for a specific paediatric use. Article 36 of that Regulation requires only that "*the product is authorised in all Member States*" and its Item 28 provides even more clearly that the paediatric extension reward "*is for conducting studies in the paediatric population and not for demonstrating that a product is safe and effective in the paediatric population, the reward should be granted even when a paediatric indication is not authorised*". Then, the SPC paediatric extension only requires that the product has been authorised in the 27 Member States regardless of the fact the authorisation is or is not for a specific paediatric use.

The Court also notes that Article 10.3 of Regulation No. 469/2009, providing that "*where the application for a certificate does not meet the conditions laid down* (…), *the authority* (…)*shall ask the applicant to rectify the irregularity* (…)", tends to indicate that the situation does not have to remain as it is at the time of filing the application but, on the contrary, may be regularised during the prosecution. And in the present case, it appears from the exhibits submitted in Court that Du Pont de Nemours forwarded to the *INPI*, at the time of filing the application for the six-month extension, a copy of the 27 MAs relating to the initial product, namely Losartan.

Finally, Mylan and Qualimed argued that the drug which they were about to launch in 2010, because it combined Losartan and HCTZ, was a different product from Losartan alone, covered by SPC No. 95C0018, and it did not therefore constitute a potential infringement of this SPC. Consequently, the preliminary injunction had been wrongly ordered and the claimants had incurred civil liability by preventing Mylan and Qualimed from entering the Losartan's market before 3 March 2010.

The *Tribunal de Grande Instance* of Paris rejects this argument holding, in accordance with the now numerous decisions of the ECJ on the issue (see ECJ, 24 November 2011, Medeva, C-322/10, pt. 39; 24 November 2011, Georgetown University, C-422/10, pt. 32; 25 November 2011, University of Queensland and CSL Ltd, C-630/10, pt. 34; 25 November 2011, Daiichi Sankyo, C-6/11, pt. 29; and especially about the Valsartan combined with hydrochlorothiazide, ECJ, 9 February 2012, Novartis, C-574/11, pts. 16 *et seq.*; 9 February 2012, Novartis, C-442/11, pts. 18

et seq.; see also our previous post), that it results from a combination of Articles 5 and 4 of Regulation No. 469/2009 that since Du Pont de Nemours as the holder of the basic patent could, during its period of validity, oppose any use or certain uses of its product (Losartan) in the form of a medicinal product consisting of such a product or containing it, the SPC granted in respect of the same product gave him the same rights over any use of the product (Losartan) as a drug, alone or in combination with other active ingredients.

In conclusion, the infringement alleged in 2010 by the claimants was indeed imminent and the provisional measures prohibiting the marketing of drugs combining Losartan and HCTZ were justified until 2 March 2010, the date upon which the validity of SPC No. 95C0018, extended by the paediatric extension, ended.

Original French decision.
English translation .

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