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Another SPC Coming

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In the UK, the signal “Another train coming” flashes when there is more than one railway line over an automatic crossing and another train is approaching. If you have avoided the first train, you must pay attention to the other train approaching not to be hit by it. We can take a similar warning from the order handed down on 12 February 2010 by the Tribunal de Grande Instance of Paris: the expiry of a SPC covering a combination of two active ingredients does not allow the exploitation of that combination if another SPC covering only one of those active ingredients is still in force: such exploitation infringes this SPC.

The American company E.I. Du Pont de Nemours and Company has two European patents relating to anti-hypertensive compounds: imidazoles acting as angiotensin II receptor blockers. The first patent covers a group of anti-hypertensive imidazoles, among which losartan, pharmaceutical compositions containing them as well as processes for the preparation of those compounds. The second patent covers pharmaceutical compositions combining anti-hypertensive imidazoles and diuretics (which by eliminating part of the water and sodium contained in blood contribute also, by decreasing blood volume, to lowering pressure level) as well as processes for the manufacturing of those compositions.

On the basis of those two European patents, E.I. Du Pont de Nemours has also obtained two supplementary protection certificates (SPC) in accordance with Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (replaced in the meantime by Regulation (EC) No. 469/2009 of 6 May 2009). Those two SPCs came into force at the respective expiry date of the two patents (on 9 July 2007 and 5 January 2009). The first SPC covered losartan while the second covered losartan in combination with hydrochlorothiazide (HTCZ), a diuretic.

As the first SPC was to expire on 2 September 2009, E.I. Du Pont de Nemours applied for and obtained a paediatric extension on the basis of Article 36 of Regulation (EC) No. 1901/2006 of 12 December 2006 on medicinal products for paediatric use. The validity of the first SPC was thus extended by 6 months to 2 March 2010.
However, the company did not apply for such an extension of the second SPC which thus was to expire on 15 February 2010.

When the generic manufacturer Mylan obtained, by way of AFSSAPS decisions on 5 June 2009, the registration of its generic drugs Losartan HTCZ Mylan 50mg and 100mg which combine the active ingredients losartan and hydrochlorothiazide, E.I. Du Pont de Nemours then warned Mylan

that putting on the market those generic drugs before the end of the first SPC extension, that is, on 2 March 2010, would amount to an infringement.
Mylan replied that it intended nonetheless to commercialise its generic drugs as of 15 February 2010, the expiry date of the second SPC which was the only one to cover the combination of losartan and hydrochlorothiazide at issue.

On 2 February 2010, E.I. Du Pont de Nemours and its exclusive licensee initiated preliminary proceedings against Mylan with an emergency motion to be heard at very short notice, for enjoining Mylan, under a penalty, from manufacturing, having manufactured, importing, offering for sale and selling, using and holding pharmaceutical compositions reproducing the characteristics covered by the claims of the first patent and of the first SPC. The summons was served on 2 February 2010 and the hearing took place on 5 February 2010.

In its order handed down on 12 February 2010, the Presiding judge of the *Tribunal de Grande Instance* of Paris decided that, although the generic drug combining losartan and a diuretic is subject to the second SPC, which covers precisely such combination of active ingredients, only until its expiry date (on 15 February 2010), this generic drug, insofar as it contains losartan acting as active ingredient against hypertension, is also subject to the first SPC, which covers losartan alone, until its respective expiry (on 2 March 2010). Such a solution must be approved. According to Article 5 of the Regulation No. 1768/92, the SPC shall confer the same rights as conferred by the basic patent. Yet, it is settled case law, in the field of patents, that patent infringement is established when the patented element can be found as such among other elements in the same litigious object.

The Judge also dismissed Mylan's argument according to which the conditions of the paediatric extension were not all met, in particular the condition of Article 36 §3 according to which the extension shall be granted only if the product is authorised in all Member States. According to Mylan, this condition presupposed that all the MAs were to be granted in each of the 27 Member States of the European Union at the time of the paediatric extension application.

Because Article 36 §3 does not expressly require that the MAs be granted at the time of the paediatric extension application, the Judge decided that those paediatric MAs, as in the present case, should be applied for on the day the application is filed as long as they are added to the file during the examination period.

Lastly, having decided that any exploitation of a drug containing losartan as a main active ingredient constitutes an infringement of the extended protection of the claims of the basic patent and of the first SPC, the Judge only enjoined Mylan from marketing its generic drugs. The judge took the view that the manufacturing, holding and importing of generic drugs before the end of the protection period of the patent would not constitute an act of infringement. Such position is questionable. According to Article 5 of Regulation (EC) No. 469/2009, the SPC shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations. Article L. 613-3 of the French Intellectual Property Code confers to the owner of the patent the exclusive right on the manufacturing, holding or importing of the product which is the subject matter of the patent. No limitation can be applied to this list. Article L. 613-5 d), the so-called Bolar provision, ("The rights afforded by the patent shall not extend to: … d) the studies and assays required to obtain a marketing authorisation for a medicinal product, as well as the acts necessary to their completion and for obtaining the marketing authorisation") allows for clinical studies not for stockpiling. This is the only point of the judgment calling for criticism.

Original French decision.
English translation.

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