FRENCH REPUBLIC
IN THE NAME OF THE FRENCH PEOPLE

***COUR D'APPEL* OF PARIS**

Section 5 - Chamber 3

DECISION OF 15 MARCH 2011

(No. 184, 10 pages)

Docket number: **10/03075**

Decision referred to the *Cour d'Appel*: order of 12 February 2010 - *Tribunal de Grande Instance* of PARIS – Docket No. 10/51453

APPELLANTS

SAS MYLAN represented by its President
117 Allée des Parcs
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SAS QUALIMED, represented by its President
117 Allée des Parcs
34 rue Saint Romain
69008 Lyon

represented by Mr Dominique Olivier, *avoué* before the *Cour d'Appel*
assisted by Mr Jean-Christophe Galloux, attorney-at-law, member of the Paris bar, courthouse: E 146

RESPONDENTS

E.I. DU PONT DE NEMOURS AND COMPANY represented by its legal representatives
1007 Market Street
Wilmington
DELAWARE 19898 United States of America

SNC LABORATOIRES MERCK SHARP & DOHME-CHIBRET represented by its legal representatives
3 avenue Hoche
75008 Paris

represented by *SCP* Monin d'Auriac de Brons, *avoués* before the *Cour d'Appel* assisted by Ms Laetitia Benard pleading on behalf of the Partnership Allen & Overy LLP, attorneys-at-law, members of the PARIS bar, courthouse J 022

COMPOSITION OF THE COURT:

The case was discussed on 31 January 2011, in public hearing, before the *Cour d'Appel*

Composed of:

Ms Joëlle Bourquard, Presiding Judge of the Chamber
Ms Martine Taillandier-Thomas, Judge
Ms Sylvie Maunand, Judge

who deliberated

Court clerk, during the discussion**:** Ms Véronique Couvet

DECISION:

- AFTER DUE HEARING OF THE PARTIES

- it was made available at the Court Clerk's office, the parties having been previously notified in accordance with the conditions laid down in the second subparagraph of Article 450 of the French Civil Procedure Code;

- it was signed by Ms Joëlle Bourquard, Presiding Judge and by Ms Véronique Couvet, Court Clerk.

• The American company EI Du Pont de Nemours and Company (hereinafter referred to as "Du Pont") is the holder of patent EP 0 253 310 entitled "Angiotensin II receptor blocking imidazoles".

A European patent application was filed on 9 July 1987 under the priority of two American patents of 11 July 1987 (US 884,920) and of 22 May 1987 (US 50,341). The grant of patent EP 310 was published by the European Patent Office on 26 October 1994.

The European patent remained in force by the regular payment of the renewal fees and expired on 9 July 2007.

It concerns a group of anti-hypertensive compounds, among which losartan, pharmaceutical compositions containing them as well as processes for the preparation of those compounds.

On 16 June 1995, Du Pont filed supplementary protection certificate (SPC) application No. 95C0018 on the basis of marketing authorisation (MA) NL 20000 granted in France on 15 February 1995 and MA NL 12 209 granted in Sweden on 2 September 1994.

SCP No. 95C0018 was granted on 17 October 1996 and its grant was published in the *BOPI (Bulletin Officiel de la Propriété Industrielle)* No. 96/45. It was to expire on 2 September 2009. It covers losartan. It remained in force by the regular payment of the renewal fees.

On 27 February 2009, Du Pont filed an application for a "paediatric extension" in accordance with Article 36 of Regulation (EC) No. 1901/2006 of 12 December 2006 on medicinal products for paediatric use.

In a decision of 6 July 2009 published in the *BOPI* No. 09/31 dated 31 July 2009, the Director of the *INPI* (*Institut National de la Propriété Intellectuelle)* accepted Du Pont's application.

The validity of SPC No. 95 C 0018 was thus extended to 2 March 2010.

Patent EP 310 was never disputed after it was granted.

Under a licence agreement between Du Pont and Laboratoires Merck Sharp & Dohme Chibret (Merck), entered in the *RNB* under No. 172 708, Merck is the holder of an exclusive licence for the French designation of patent EP 310 and of an exclusive licence for SPC No. 95 C 0018.

Du Pont is also the holder of patent EP 0 733 366 entitled "Pharmaceutical compositions comprising angiotensin II receptor blocking imidazoles and diuretics" which was filed on 5 January 1989 and the grant of which was published at the EPO on 1 April 1998. This patent expired on 5 January 2009.

On 14 August 1998, Du Pont filed SPC application No. 98C0025 on the basis of marketing authorisation NL 20037 granted in France on 15 February 1995.

SPC No. 98C0025 was granted on 6 April 2001. It covers losartan in combination with hydrochlorothiazide (HCTZ). It expired on 15 February 2010.

Merck is the holder of the MA for the proprietary drugs containing losartan. It commercialises these drugs in France under the brand name "Cozaar" and under the brand names "Hyzaar" and "Fortzaar" for losartan plus a diuretic, at different dosages.

Mylan obtained the registration of its generic drugs Losartan HCTZ Mylan 50mg and 100mg by decisions of the Afssaps on 5 June 2009; these drugs contain the two active ingredients losartan and HCTZ.

In a registered letter with acknowledgment of receipt dated 22 July 2009, Merck warned Mylan against the placing on the market of these losartan-based drugs before 2 March 2010, the expiry date of its SPC.

On 26 January 2010, Mylan, on behalf of Qualimed, replied by arguing that the proprietary drugs containing only losartan and losartan combined with hydrochlorothiazide constitute distinct products and that only SPC 95C0018 has obtained a paediatric extension so that SPC No. 98C0025 is not covered by this extension.

In another letter dated 27 January 2010, Merck reiterated its warning.

On 2 February 2010, Du Pont and Merck summoned Mylan and Qualimed to appear in preliminary proceedings with an emergency motion to be heard at very short notice, for the purposes of enjoining the latter, under a penalty, from selling pharmaceutical compositions reproducing the characteristics covered in particular by claims 1, 2, 3, 4 and 5 of patent EP 0 253 310 and of SPC No. 95C0018 and of ordering them to pay the sum of €100,000 pursuant to Article 700 of the French Civil Procedure Code, before the Judge of the *Tribunal de Grande Instance* of Paris, ruling in preliminary proceedings, who, by an order dated 12 February 2010, had enjoined Mylan and Qualimed from offering for sale and from selling, that is, from marketing these pharmaceutical compositions and in particular losartan HCTZ Mylan 50mg and 100mg

reproducing the characteristics covered in particular by claims 1, 2, 3, 4 and 5 of patent EP 0 253 310 and of SPC No. 95C0018 before 2 March 2010, under a penalty of €100 per tablet offered for sale and sold in bulk or in any other packaging form, the penalty taking effect as of the day the order is handed down; the judge ruling in preliminary proceedings reserved the right to set the penalty to be ordered, dismissed all Mylan and Qualimed's counterclaims and ordered them jointly and severally to pay the overall sum of €15,000 on the basis of Article 700 of the French Civil Procedure Code.

In a pleading dated 21 January 2011, Mylan and Qualimed, the appellants, request that the Judge:

- hold that they did not commit any act of infringement by placing on the market their drug losartan HCTZ on 15 February 2010;

- find that the requirements for obtaining an extension of the duration of the protection provided by SPC No. 95C0018 as laid down in Article 36 of Regulation (EC) No. 1901/2006 are not met;

- consequently dismiss all Du Pont and Merck's claims;

- in the alternative, remit the case to the Court of Justice of the European Union pursuant to Article 267 of the Treaty on the Functioning of the European Union so as to refer to that Court the following questions for a preliminary ruling:

1) Does Article 4 of Regulation (EC) No. 469/2009 of 6 May 2009 permit to assert a SPC covering a proprietary drug comprising one single active ingredient (compound A) in order to prevent the manufacturing and/or the marketing of a drug comprising this active ingredient in combination with another active ingredient (compounds A+B),

although under this same article, the protection conferred by the SPC extends only to the product covered by the MA for the corresponding medicinal product,

the pharmaceutical regulatory requirements impose to obtain an MA for a medicinal product comprising only one active ingredient and a distinct MA for a medicinal product comprising the same active ingredient (compound A) in combination with another active ingredient (compounds A+B),

Article 1b of the same regulation defines the product as the active ingredient or the combination of active ingredients of a medicinal product?

2) If the answer to question 1 is "yes", could the paediatric extension be obtained pursuant to Regulation (EC) No. 469/2009 on the basis of paediatric tests carried out on a product comprising only one active ingredient (compound A) be asserted and prevent the manufacturing and/or the marketing of a product comprising this active ingredient in combination with another active ingredient (compounds A+B) although this product would not have been subject to paediatric tests and that the conditions of Article 36, 1 to 2, of Regulation (EC) 1901/2006 would not be met? Must the notion of product referred to in Article 36, subparagraph 4 of Regulation (EC) 1901/2006 be construed in the light of Article 1(b) of Regulation (EC) No. 469/2009?

3) Does Article 36(3) of Regulation (EC) 1901/2006 of 12 December 2006 relating to the medicinal products for paediatric use require that the product be granted in all the Member

States a paediatric MA containing the results of the studies conducted in the paediatric population? If so, is it a substantive condition requiring that a paediatric MA be obtained in all the Member States at the date on which the application for the SPC extension is filed or is it a formal condition enabling the application for the SPC extension to be rectified after its filing and the MAs granted during the examination of the said application to be filed?

In any case, the appellants request that the Judge order Du Pont and Merck jointly and severally to pay to Mylan and Qualimed the sum of €50,000 on the basis of Article 700 of the French Civil Procedure Code.

In their pleading dated 25 January 2011, Du Pont and Merck request that the Court affirm the appealed order and rule again by holding that the interlocutory injunction should have been extended to the acts of manufacturing, importing, using and holding any pharmaceutical product containing losartan reproducing claims 1 to 5 of patent EP 0 253 310 and of SPC No. 95C0018 until 2 March 2010, dismiss the appellants' claims and order the latter to pay them the sum of €100,000 for the irrecoverable costs.

WHEREUPON, THE COURT

Considering that the claims made on the basis on Article L. 615-3 of the French Intellectual Property Code provides that "Any person with authority to bring an action for infringement may, in preliminary proceedings, request the competent civil court to order, under 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…The court, in preliminary or *ex parte* proceedings, may order the requested measures only if evidence, reasonably accessible to the claimant, make it likely that its rights are infringed or that such infringement is about to be committed";

Considering that the procedure provided for by these provisions is independent and its conditions of application are different to those laid down in Articles 808 and 809 of the French Civil Procedure Code;

Considering that in the light of the legislation applicable to this case, Du Pont and Merck should demonstrate that on the basis of the evidence that they may have and with respect to the industrial property rights which they own, an infringement of their rights, by the manufacture and the sale of a generic drug by Mylan and Qualimed is likely or imminent;

Considering that the appellants dispute the fact that SCP No. 95C0018 extended by the decision of 6 July 2009 until 2 March 2010 may be asserted against them to prohibit the manufacturing and selling their generic drugs before that date;

Considering that they dispute the validity of the extension granted in France on 6 July 2009 by the *INPI* by reference to Article 13(3) of Regulation (EC) 469/2009 and Article 36 of Regulation (EC) 1901/2006; they reproach Du Pont for not demonstrating that all the paediatric MAs had been granted in the 27 States of the European Union at the time of the filing of the application for the

paediatric extension;

Considering, in fact, that SCP No. 95C0018 was granted on 17 October 1996 to expire on 2 September 2009 and that a paediatric extension in application of Article 36 of Regulation (EC) No. 1901/2006 was granted enabling losartan to be protected until 2 March 2010;

Considering that the extension of the period of protection granted in this context is a reward for carrying out paediatric studies but does not mean that the product is necessarily efficient in the paediatric population and that the extension of the period of protection may be granted although the paediatric indication is not authorised;

Considering that pursuant to the aforementioned Article 36, the application for an extension includes the result of the studies conducted according to an approved paediatric investigation plan and the six-month extension of the period is granted only if the product is authorised in all the Member States;

Considering that the text which only mentions the fact that the product is authorised, does not specify that during the filing of the application, all the paediatric MAs must have been obtained; in fact, to request that the 27 paediatric MAs be supplied on the date of the filing of the application is not possible in practice in the absence of a centralised procedure of registration and owing to the variable speed at which agencies grant these authorisations; the text can only refer to the requirement of supplying the initial MAs, since the paediatric MAs can be supplied during the grant procedure of the SPC extension; it moreover must be noted that this position was finally adopted by the *INPI* as confirmed by the circular from the pharmaceutical industry union dated 7 January 2011;

Considering that Du Pont filed its application for an SPC extension on 27 February 2009 and that the copy of the MAs for all the other Member States were among the attached exhibits; it follows that the procedure is properly conducted and that the extension of the period of protection granted further to this application need not be cancelled.

Considering that SCP No. 95C0018 was valid until 2 March 2010;

Considering that it follows that until that date, any manufacturing or marketing of the medicinal products claimed and protected by this right is prohibited.

Considering that the regulation applicable to the dispute is Regulation (EC) No. 469/2009 of 6 May 2009 and that in any event, the discussion relates to Articles 4 and 5 of this regulation which are identical to those of Regulation (EC) No. 1768/92 cited in the proceedings;

Considering that the definitions of the terms referred to in this regulation must be recalled;

Considering that the medicinal product means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

Considering that the product is the active ingredient or the combination of active ingredients;

Considering that Article 4 of the regulation concerns the subject-matter of protection of the certificate and provides that "within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product 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"; Article 5 supplements it by stating the effects of the certificate and providing that "subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations";

Considering that the parties admit that these Articles must be read in combination;

Considering that the basic patent is the patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;

Considering that the basic patent is entitled "Angiotensin II receptor blocking imidazoles" and relates to the angiotensin receptor blockers, a group of anti-hypertensive agents; claims 1 to 5 of the patent cover losartan;

Considering that the supplementary protection certificate which was extended until 2 March 2010 relates to losartan potassium which is therefore the product covered by the MA.

Considering that the appellants do not dispute the fact that the two products Losartan HCTZ 50mg and 100mg are generic drugs within the meaning of Article L 5121-1, subparagraph 5 of the French Public Health Code, namely a medicinal product which has the same qualitative and quantitative combination of active ingredients as the proprietary medicine, the same pharmaceutical form, and whose bioequivalence with the proprietary medicine is demonstrated by the relevant bioavailability studies;

Considering that MYLAN and QUALIMED dispute any infringement of the rights asserted against them by their products since the generic drugs which they intend to sell, contain losartan and another active ingredient, the HCTZ; they consider that only the product protected by the SPC cited by the respondents is losartan and that proof has been given that there is no infringement since the respondents have been granted another SPC relating to losartan combined to a diuretic which means that the products are distinct;

Considering that it must be pointed out that under French law, infringement is assessed over similarities and not merely over differences so that characteristics added to the characteristics claimed by a patent do not take away the infringement;

Considering that the supplementary protection certificate which aims at supporting innovation in the field of health, confers protection to a product as a medicinal product in all the forms falling within the scope of protection of the basic patent;

Considering that in this instance, the certificate which is extended confers the same rights as those

of the basic patent relating to losartan and the protection conferred by this certificate relates to the product covered by the AM and does so for any use of the product as a medicinal product that was authorised before the expiry of the certificate; it follows that the protection concerns any use of losartan as a medicinal product;

Considering that the existence of another SPC whose protection has expired is immaterial in this instance, that SPC No. 98C0025 corresponded to another MA relating to losartan potassium and hydrochlorothiazide and therefore to the protection of a different medicinal product even if losartan was contained therein; two distinct SPCs and two distinct basic patents can correspond to two MAs; in any case, the relevant products were different and these different products had been the subject-matter of two distinct protections;

Considering that on 5 June 2009, Mylan had been granted MAs relating to the pharmaceutical products Losartan HCTZ 50 et 100mg; these are generic drugs which are pharmaceutical products with the same qualitative and quantitative combination of active ingredients as the proprietary medicine and the same pharmaceutical form; in this instance, these medicinal products contain losartan as a drug;

Considering in fact, that the Afssaps in its index of pharmaceutical products updated on 29 January 2010 mentions for the appellants' two products that their composition for one tablet contains potassic losartan and HCTZ, and that the medicinal product is indicated in the case of high blood pressure;

Considering that it follows that the generic drugs which Mylan and Qualimed intended to place on the market could constitute, should this placing on the market take place before 2 March 2010, an infringement of the product protected by SPC No. 95C0018 since they contained losartan;

Considering that Du Pont and Merck indicate that on 30 October 2009 Mylan and Qualimed obtained the registration of their products in the index of pharmaceutical products refundable to persons paying the social security contributions, then on 10 November 2009 an opinion on their selling price and on 17 September 2009 their registration in the repertory of generic drugs;

Considering that on 22 July 2009, Merck sent a warning letter to the two appellants recalling their rights and the impossibility for them to manufacture, offer, sale, use, import or hold the products thus protected until the expiry dates of these rights;

Considering that on 26 January 2010 Mylan replied that it did not agree with Du Pont's reasoning and that it disputed the claimed protection considering that the supplementary protection certificate of losartan combined to HCTZ expired on 15 February 2009; it added that it reserved the right to take any action aiming at enforcing its rights and in particular against obstacle to the penetration of generic drugs;

Considering that the respondents consider that it results from these facts that an imminent infringement of their rights was thus demonstrated justifying the requested measures;

Considering that is imminent an infringement which has not yet been committed but which is bound to happen, should the current situation continue;

Considering that the legislator authorised generic manufacturers to take all the necessary formalities to place on the market their products before the extinguishment of the intellectual property rights over the proprietary drugs as provided for in Article 5121-10 of the French Public Health Code; even if they can have their product registered in the list of refundable medicinal products and in the index of generic drugs; these formalities are completed subject to notification of the right holder;

Considering therefore that the mere fact that the attempts in accordance with these legal provisions were made by Mylan and Qualimed before the expiry of the rights of Du Pont and Merck is not sufficient to demonstrate the imminent infringement of the latter's rights;

Considering that the simple warning letter sent by the right holders to the appellants is neither conclusive;

Considering, likewise, that Mylan's reply disputing the analysis of the rights which Du Pont and Merck made, and particularly concerning the second SPC No. 98C0025 is not sufficient to consider that the latter's rights were about to be infringed and that potential acts of infringement were committed before 2 March 2010;

Considering that, as it stands, the respondents do not provide any evidence, for the subsequent period from 15 February to 2 March 2010, that preparations were made for manufacturing or marketing during that period, for distributing brochures or advertisements announcing the launching of the products, the visit of medical doctors in view of the prescription of these generic drugs; in the absence of such elements relating to the setting up of some manufacturing, door-to-door selling or advertisement and although the summons had been served on 2 February 2010 and that the SPC was to expire on 2 March 2010, the probability of this manufacturing and this selling being set up within such a short period of time seems somehow unlikely;

But considering that in their own pleading, Mylan and Qualimed, before the *Cour d'Appel*, claim that they did not market their medicinal products, did not make preparations for any marketing before 15 February 2010 and did not commit acts of infringement by placing on the market their medicinal products on 15 February 2010; it emerges from this statement that they implicitly admit having, after 15 February 2010, placed on the market the generic drugs accused of infringement by the respondents; through this admission the imminent infringement is demonstrated;

Consequently, the appealed order must be affirmed in that it prohibits the marketing of Losartan HCTZ 50mg and Losartan HCTZ 100mg until 2 March 2010; the respondents' request for the prohibition of the manufacturing, the holding, the use or import of these medicinal products before that date cannot be accepted since these are generic drugs which were granted the required authorisations from the public authorities and which should be marketed as of the end of the protection conferred by the patent and the SPC held by the respondents; only marketing before expiry of the protection may be considered to be an infringement;

Considering none the less that owing to the court's findings stated above the penalty appears to be

neither necessary nor appropriate and the order will be reversed for that reason;

Considering, therefore, that there is no grounds for examining further the factual and legal arguments raised by the parties and in particular the argument drawn from the opportunity to refer a question for a preliminary ruling to the ECJ;

Considering that fairness does not require that the parties' request made on the basis of Article 700 of the French Civil Procedure Code be accepted;

Considering that the factual circumstances justify that each of the parties bear its own expenses incurred during these proceedings;

ON THESE GROUNDS:

Affirms the appealed order except concerning the pronouncement of a penalty;

Ruling again

Holds that the penalty need not be ordered;

Dismisses all the parties' other claims;

Dismisses any claim lodged by the parties on the basis of Article 700 of the French Civil Procedure Code;

Holds that each party should bear its own appeal expenses.

THE COURT CLERK THE PRESIDING JUDGE