TRIBUNAL DE GRANDE INSTANCE OF PARIS

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ORDER IN PRELIMINARY PROCEEDINGS
handed down on 12 February 2010

Docket No.: **10/51453**

No.: 1/FB

Summons of:
2 February 2010

by Ms **Marie-Christine Courboulay,** Vice Presiding Judge at the Tribunal *de Grande Instance* of Paris, who held the public hearing in the preliminary proceedings acting on behalf of the President of the *Tribunal*,

Assisted by Ms **Stéphanie Nabot,** Chief Court Clerk.

CLAIMANTS

E.I DU PONT DE NEMOURS AND COMPANY
1007 Market Street, Wilmington, Delaware
19898 United States of America

S.N.C. LABORATOIRES MERCK SHARP & DOHME-CHIBRET
3 avenue Hoche 75008
Paris
France

represented by Mr Pierre Lenoir, attorney-at-law,
member of the Paris Bar - J22

DEFENDANTS

S.A.S MYLAN
117, Allée des Parcs
69792 Saint-Priest Cedex
France

represented by:
Mr Jean Christophe Galloux, attorney-at-law,
member of the Paris bar -E0146
Ms Karine Étienne, *SCP* Lamy & Associés,
member of the Lyon Bar,
domiciled at 40 rue de Bonnel 69003 Lyon, France

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DISCUSSION

At the hearing of 5 February 2010, held publicly and presided by Ms Marie-Christine Courboulay, Vice-Presiding Judge,

We, Presiding Judge,

After hearing the parties appearing before the Court or their attorneys-at-law,

THE FACTS AND THE PARTIES' CLAIMS

The American company E.I Du Pont de Nemours and Company is the holder of European patent No. 0 253 310 entitled "Angiotensin II receptor blocking imidazoles".

The 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 EPO on 26 October 1994.

Patent EP 310 remained in force by the regular payment of the renewal fees and expired on 9 July 2007.

It concerns a group of hypertensive[1] compounds, among which losartan, pharmaceutical compositions containing them as well as processes for the preparation of those compounds.

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

SPC No. 95C0018 was granted on 17 October 1996 and its grant was published in the *Bulletin Officiel de la Propriété Industrielle (BOPI*) No. 96/45. It covers losartan.

It remained in force by the regular payment of the renewal fees and was to expire on 2 September 2009.

[1] Translator's note: the correct term should read "anti-hypertensive"

On 27 February 2009, Du Pont de Nemours and Company 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*[2] accepted Du Pont de Nemours and Company's application.

The validity of SPC No. 95C0018 was thus extended to 2 March 2010.

Patent EP 310 was not challenged in any way during the time elapsed since its grant.

In accordance with a licence agreement signed on 3 September 2009 by Du Pont de Nemours and Company and Laboratoires Merck Sharp & Dohme-Chibret, and entered in the *RNM*[3] on that date under No. 172 708, Laboratoires Merck Sharp & Dohme–Chibret is the holder of an exclusive licence of the French designation of patent EP 310 and of an exclusive licence for SPC No. 95C0018.

Du Pont de Nemours and Company was also the holder of European patent No. 0 733 336 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 EP 366 expired on 5 January 2009.

On 14 August 1998, Du Pont de Nemours and Company filed a 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 2010. It covers losartan in combination with hydrochlorothiazide. It is to expire on 15 February 2010.

Laboratoires Merck Sharp & Dohme–Chibret is the holder of the MA for the proprietary drugs containing losartan. It commercialises these drugs in France under the brand name "Cozaar" for losartan 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 HTCZ Mylan 50mg and 100mg by way of the AFSSAPS' decisions on 5 June 2009; these proprietary drugs contain the two active ingredients losartan and HTCZ.

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[2] Translator's note: *INPI* stands for *Institut National de la Propriété Intellectuelle*, the French patent office.

[3] Translator's note: *RNM* stands for *Registre National des Marques*, the French trade mark register; the correct acronym should be RNB, i.e. *Registre National des Brevets*, the French patent register.

In a registered letter with acknowledgement of receipt dated 21 July 2009, Laboratoires Merck Sharp & Dohme–Chibret warned Mylan and Qualimed against the placing on the market of their losartan-based drugs before the end of their SPC extension, that is, on 2 March 2010.

On 26 January 2010, Mylan, in the name of Qualimed, sent a letter to the claimants' attorneys-at-law in which it claimed that the proprietary drugs containing only losartan, on the one hand, and those containing losartan combined with hydrochlorothiazide, on the other hand, constitute different products and that only SPC 95C00018 had obtained a paediatric extension so that SPC 98C0025 was not covered by this paediatric extension.

It explained that it thus intended to commercialise a generic drug of Hyzaar and Fortzaar as of 15 February 2010 for which it has obtained an MA and a selling price.

In a letter dated 27 January 2010, Laboratoires Merck Sharp & Dohme – Chibret reiterated its warning.

It is under these conditions that on 2 February Du Pont de Nemours and Company and Laboratoires Merck Sharp & Dohme-Chibret 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 defendants from manufacturing, having manufactured, importing, offering for sale and selling, using and holding pharmaceutical compositions reproducing the characteristics covered in particular by claims 1, 2, 2[4], 4, and 5 of European patent No. 0 253 310 and of SPC No. 95C0018, under a €100 penalty per tablet manufactured, imported, offered for sale, sold, used or held in bulk or in any other packaging form, as of the date of service of the judgment to be handed down.
reserving the right to set the penalty to be ordered.
ordering Mylan and Qualimed, jointly and severally, to pay to Du Pont de Nemours and Company and Laboratoires Merck Sharp & Dohme – Chibret the sum of €100,000 pursuant to Article 700 of the French Civil Procedure Code.
ordering Mylan and Qualimed, jointly and severally, to pay the entire costs which Mr Pierre Lenoir, attorney-at-law, will be able to recover in accordance with the provisions laid down in Article 699 of the French Civil Procedure Code.

In support of their claims, they argued that the Judge in preliminary proceedings has jurisdiction to rule upon the case, since the threat of an imminent infringement of the claimants' rights is established.

[4] Translator's note: it should read "3" instead of "2"

They maintained that the patent covering losartan can be put forward against any product containing losartan including a product containing losartan and another product such as a diuretic; that the infringement is assessed over similarities and not differences.

They added that, on the one hand, by virtue of Article 5 of Council Regulation (EEC) No. 1768/92 applicable to SPCs, the certificate confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations, and, on the other hand, by virtue of the Article 4 of the same Regulation, the protection conferred by a SPC extends only to the product covered by the MA and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

They disputed the defendants' request for a deposit on the ground that they could afford to pay the possible alleged damages.

During the 5 February 2010 hearing, Mylan and Qualimed requested that the Judge in preliminary proceedings:
Hold that Mylan and Qualimed do not commit any act of infringement by placing on the market their drug losartan HCTZ on 15 February 2010.
Consequently,
Dismiss all the claimants' claims.
Acknowledge that the conditions under which the extension of SPC No. 95C0018 was granted, as set forth in Article 36 of Regulation (EC) No. 1901/2006, are not met.
Acknowledge that Mylan and Qualimed could not enter the market.
Assess the consequent loss of turnover to the sum of 2 million euros.
Order that an advance payment of an equal amount be made.
Subsidiarily,
Order the claimants to pay a deposit of that sum.
Grant Mylan and Qualimed the benefit of the provisions laid down in Article 811 of the French Civil Procedure Code.
Order Du Pont de Nemours and Company to pay them the sum of €50,000 on the basis of Article 700 of the French Civil Procedure Code.
Order Du Pont de Nemours and Company to pay the entire legal costs which will be recovered by Mr Galloux, attorney-at-law.

They maintained that the extension of the SPC duration obtained by Du Pont de Nemours and Company was not valid and that, as a consequence, it unnecessarily prevented them from having access to the market causing them a damage for which they are requesting compensation by way of an advance payment.

They added that only Regulation (EC) No. 469/2009 was applicable to the facts relating to the present case and that Article 5 of that Regulation should be read in combination with Article 4 of the same Regulation, which provides a solution contrary to that formulated by Du Pont de Nemours and Company.

Therefore, they specified that only the drug losartan can be granted a protection through the paediatric extension so that the losartan/HCTZ combination is not covered by any paediatric extension.

They added that they disputed the paediatric extension granted on the ground that Article 15a[5] of Regulation (EC) No. 469/2009 replacing Regulation (EEC) No. 1768/92 had not been complied with; it is not demonstrated that all the MAs had been granted in each of the 27 Member States of the European Union at the time of this application.

WHEREUPON

On the claims made before the Judge in preliminary proceedings.

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 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…*
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".*

Therefore, the case is referred to the Judge in preliminary proceedings under the same conditions as those provided in Article 809 of the French Civil Procedure Code which allows the Judge in preliminary proceedings, even when confronted with a serious challenge, to order protective measures or measures to restore the parties to their previous state as required, either to avoid an imminent damage or to abate a manifestly illegal nuisance.

The defendants do not dispute the jurisdiction of the Judge in preliminary proceedings owing to the fact that the market entry of their drugs LOSARTAN HTCZ MYLAN 50mg and 100mg before 2 March 2010 may constitute "*an infringement about to be committed against the rights conferred by the title"*.

However, the Judge in preliminary proceedings must then decide upon challenges which are brought before him with a view to opposing the requested measures and these challenges can concern the validity of the title itself; the judge should then determine the seriousness of the challenge so as to prevent the use of preliminary proceedings to obtain serious prohibition measures which would distort free competition, on the basis of a title which is too weak.

The Judge in preliminary proceedings should, when confronted with a serious challenge, weigh opposing interests so as to ensure that a balance between the rights of the parties is maintained, that is, between the seriousness of an imminent damage and its potential compensation and the seriousness of the prohibition measure sought.

[5] Translator's note: The reference to "*Article 15a"* is erroneous. It should probably read "*Article 8*".

First, the defendants maintain that the scope of the SPC as mentioned by the claimants is not correct.

If it is true that the Regulation applicable to the dispute is Regulation (EC) No. 469/2009 of 6 May 2009, it should be pointed out that the Articles cited in this dispute are the same, including their numbering, as those of Regulation (EEC) No. 1768/92, so that the discussion is undoubtedly about Articles 4 and 5 of Regulation (EC) No. 469/2009.

Article 5 of Regulation (EC) No. 469/2009 establishes that, subject to Article 4, the certificate confers the same rights as conferred by the basic patent and that it is subject to the same limitations and obligations.

Article 4 specifies that within the limits of the protection conferred by the basic patent, the protection conferred by a SPC extends only to the product covered by the corresponding MA, for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

None of the parties disputes that those two Articles should be read together and it should be added that SPC No. 95C0018 only protects losartan and no other drug.

It is neither disputed that the paediatric extension was granted only for losartan and not for losartan combined with a diuretic so that only SPC No. 95C0018 had its validity extended by 6 months that is, until 2 March 2010.

In addition, on 6 April 2001, Du Pont de Nemours and Company obtained another SPC No. 98C0025 for its pharmaceutical compositions “Hyzaar” and “Fortzaar”, on the basis of the authorisation NL 20037 to place on the market losartan combined with a diuretic.

This SPC is to expire on 15 February 2010 and prevents any commercialisation of the drugs claimed by the defendants.

The claimants merely sustain that, owing to the extended patent protection for just the drug losartan until 2 March 2010, any product placed on the market implementing in particular the claims of EP patent 310 disclosing losartan constitutes an infringement, even if the new product has additional characteristics.

As a result of the extended protection of claims 1, 2, 2, 4, and 5 of European patent No. 0 253 310 and of SPC No. 95C0018, for the losartan product only, any exploitation of a drug containing losartan as a main active ingredient obviously constitutes an infringement of those claims.

Because there is a possibility that the infringement becomes evident as a result of the entry on the market of Mylan’s drugs before 2 March 2010, the infringement is therefore proved.

Secondly, the defendants challenge the validity of the paediatric extension granted in France by the *INPI* on 6 June 2009 on the ground that point 3 of Article 15a[6] of Regulation (EC) No. 469/2009 replacing Regulation (EEC) No. 1768/92 was not complied with in this particular case, for it was not established that all the MAs had been granted in each of the 27 Member States of the European Union at the time of this application for paediatric extension.

The claimants submit to the court the grant document of the paediatric extension as granted by the *INPI* in which it appears that the copy of the national MAs of all the other Member States had been included in the file.

They also adduce the decision of the Irish Patent Office which found that all the MAs were included in the file and granted the extension with effect until 2 March 2010; the English Court of Appeal's decision issued on 17 September 2009 involving Du Pont de Nemours and Company and the UK Patent Office which states that all the MAs had been granted during the examination period before the Patent Office.

Thus, it should be said that Du Pont de Nemours and Company provides enough evidence that it had obtained a paediatric MA in the 27 Member States of the European Union and that the text adduced by the defendants does not specify that the MAs should be granted on the day the application is filed if the application is not to be rejected.

The paediatric MAs should be applied for on the day the application is filed but can be added to the file during the examination period.
Du Pont de Nemours and Company fulfilled this condition in this manner.

Finally, Mylan and Qualimed did not lodge an appeal before the *Cour d'Appel* of Paris against the *INPI*'s decision in view of challenging the decision to extend the SPC No. 95C0018 protection, decision they were informed of in the warning letter which was sent to them on 21 July 2009.

Consequently, the conditions of Article L. 615-3 of the French Civil Procedure Code are met and the claims of Du Pont de Nemours and Company and of Laboratoires Merck Sharp & Dohme-Chibret will be accepted within the terms of the operative part of the decision, specifying that only the commercialisation of the drugs LOSARTAN HTCZ MYLAN 50mg and l00mg will be prohibited until 2 March 2010 since manufacturing, holding and importing generic drugs before the end of the protection period of the patent does not constitute an act of infringement.

[6] Translator's note: The reference to "*Point 3 of Article 15a"* is erroneous. It should read "*Paragraph 3, Article 8*".

On Mylan and Qualimed's counterclaims.

* the advance payment

The documents of the file show that the patents and SPCs protecting losartan and losartan combined with a diuretic were never challenged as to their validity, that the protection of losartan combined with a diuretic had been extended to 15 February 2010 so that the claimants do not prove that they have suffered a damage as result of an anti-competitive practice before 15 February 2010; that the claimants' request for an injunction concerns a 15 days' period and that it has been held above that the request for an injunction was well-founded.

Mylan and Qualimed's request for an advance payment will be dismissed.

* the deposit

In the present case, the defendants do not demonstrate that they have suffered a damage as a result of the prohibition measure and in any case, if a decision on the merits of the case granted them damages after considering that this measure had been unduly obtained by the claimants, it is not demonstrated that the recovery of these damages would meet any difficulty on the one hand because one of the claimants is a French company and on the other hand because it is not alleged that it would be unable to pay the required sums.

Mylan and Qualimed's request for an advance payment will be dismissed.

* hearing in view of a ruling on the merits of the case

Finally, the defendants request that the judge schedule the matter to a hearing, the date of which will be specified by him, in view of a ruling on the merits of the case, on the basis of Article 811 of the French Civil Procedure Code.

Yet, Mylan and Qualimed's request does not fulfil the condition of emergency set out in that article since the dispute relating to the validity of the grant of the title by the *INPI* can only be referred to the *Cour d'Appel* of Paris so that this request will be dismissed too.

On the other claims.

The conditions are met to grant to Du Pont de Nemours and Company and to Laboratoires Merck Sharp & Dohme – Chibret the sum of €15,000 on the basis of Article 700 of the French Civil Procedure Code.

The request made to the Judge ruling in preliminary proceedings for the recovery of the court costs incurred is ill-founded, this provision set out in Article 699 of the French Civil Procedure Code being applicable only when the attorney-at-law's ministry is mandatory.

ON THESE GROUNDS

Ruling by way of an order handed to the Court clerk, after hearing both parties and in first instance,

Enjoin Mylan and Qualimed from offering for sale, selling, that is, from commercialising pharmaceutical compositions and in particular LOSARTAN HTCZ MYLAN 50mg and 100mg reproducing the characteristics covered in particular by claims 1, 2, 2, 4, and 5 of European patent No. 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 on the day the order is handed down.

Reserve the right to set the penalty to be ordered.

Dismiss all Mylan and Qualimed's counterclaims.

Order Mylan and Qualimed, jointly and severally, to pay the overall sum of €15,000 to Du Pont de Nemours and Company and Laboratoires Merck Sharp & Dohme – Chibret on the basis of Article 700 of the French Civil Procedure Code.

Add that this order is provisionally enforceable.

Dismiss the parties' additional claims.

Order Mylan and Qualimed, jointly and severally, to pay the legal costs.

Drafted in Paris, on the Twelfth of February Two Thousand and Ten

The Court clerk, The Presiding Judge,

Stéphanie Nabot Marie-Christine Courboulay