T R I B U N A L
D E G R A N D E
I N S T A N C E
O F P A R I S

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3rd chamber 2nd section

Docket No.:
10/04262

Original copy No.: 1

Summons of:
11 March 2010

JUDGMENT
handed down on 8 June 2012

CLAIMANTS

E.I. DU PONT DE NEMOURS & COMPANY
1007 Market Street,
Wilmington, Delaware 19898
(UNITED STATES OF AMERICA)

LABORATOIRES MERCK SHARP & DOHME-CHIBRET SNC
3 avenue Hoche
75008 PARIS

represented by Mr Pierre LENOIR, attorney-at-law, member of the PARIS Bar, courthouse box # J022 and Ms Laëtitia BENARD, attorney-at-law, member of the PARIS Bar, courthouse box J22

DEFENDANTS

MYLAN S.A.S.
117, Allée des Parcs
69792 SAINT-PRIEST
CEDEX
FRANCE

represented by Mr Jean-Christophe GALLOUX, attorney-at-law, member of the PARIS Bar, courthouse box E0146

Enforceable copies issued on: 8/6/2012

QUALIMED
34, rue Saint Romain
69008 LYON
FRANCE

represented by Mr Jean-Christophe GALLOUX, attorney-at-law, member of the PARIS Bar, courthouse box E0146

COMPOSITION OF THE COURT

Véronique RENARD, Vice-Presiding Judge, *who signed the decision*
Eric HALPHEN, Vice-Presiding Judge
Valérie DISTINGUIN, Judge

assisted by Jeanine ROSTAL, acting as Court Clerk, *who signed the decision*

DISCUSSION

At the hearing of 4 May 2012
held publicly

JUDGMENT

Pronounced by delivery of the decision at the Court Clerk's office
After due hearing of the parties
in first instance

FACTS, PROCEEDINGS AND THE PARTIES' CLAIMS

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*, applied for on 9 July 1987, claiming priority from two US patent applications. The mention of the grant of the patent was published in the European Patent Bulletin on 26 October 1994. The patent, which related to a group of antihypertensive compounds, including Losartan, expired on 9 July 2007.

DU PONT DE NEMOURS & COMPANY was also the holder of SPC No. 95C0018, granted on 17 October 1996, which also covered Losartan. An application for a "paediatric extension" of this SPC, whose initial expiry was 2 September 2009, was filed and granted by the Director of the *INPI* on 6 July 2009, resulting in the SPC's ensuing expiry on 2 March 2010.

Pursuant to a licence agreement reached on 3 September 2009 and entered in the French patent register on that date under No. 172708, LABORATOIRES MERCK SHARP & DOHME-CHIBRET (hereinafter referred to as "MERCK") became the holder of an exclusive licence of the French designation of the said patent and SPC. This company is

also the holder of the marketing authorisation for the pharmaceutical drugs containing Losartan and markets these drugs 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 MYLAN and QUALIMED by way of a summons dated 2 February 2010, for provisionally enjoining them from manufacturing and marketing any pharmaceutical product containing Losartan. In an order dated 12 February 2010, the Presiding Judge of this Court 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*".

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.

By way of a summons of 2 March 2010, MYLAN and QUALIMED brought proceedings against DU PONT DE NEMOURS for the invalidity of the SPC extension. By way of an order dated 22 September 2011, the two proceedings were consolidated.

In their recapitulative pleading notified on 5 April 2012, to which it is expressly referred, DU PONT DE NEMOURS and MERCK, after refuting the arguments presented in defence, request that the *Tribunal*:

- hold that the request for a stay of the proceedings lodged by MYLAN and QUALIMED by way of a pleading on 15 March 2012 is inadmissible and should be dismissed,
- validate the 12 February 2010 order of the President of the *Tribunal de Grande Instance* of PARIS affirmed by the *Cour d'Appel* of PARIS on 15 March 2011,
- hold that the preliminary injunction should have applied to the acts of manufacturing, importing, using and holding for such purposes any drug containing Losartan, reproducing claims 1 to 5 of European patent No. 0 253 310 and SPC No. 95C0018 extended to 2 March 2010,
- dismiss MYLAN and QUALIMED's claim for invalidity of the six-month extension of SPC No. 95C0018,
- dismiss MYLAN and QUALIMED's request for compensation,

- dismiss all of MYLAN and QUALIMED's claims, and arguments;

- order, jointly and severally, MYLAN and QUALIMED to pay them the sums of €214,083.45 and $320,939.36 pursuant to Article 700 of the French Code of Civil Procedure, subject to adjustment,

- order, jointly and severally, MYLAN and QUALIMED to pay the entire costs and hold that they will be recovered directly by Mr Pierre LENOIR, attorney-at-law, pursuant to the provisions laid down in Article 699 of the French Code of Civil Procedure,

- order the provisional enforcement of the judgment to be handed down.

In their latest pleading of 30 March 2012, to which it is also referred, MYLAN and QUALIMED request that the *Tribunal*:

- stay the proceedings pending the decision of the *Cour de Cassation* on appeal No. B 11-17.318,

- in the alternative,

- acknowledge that the drugs LOSARTAN HCTZ MYLAN 50 mg and 100 mg and LOSARTAN HCTZ QUALIMED 50 mg and 100 mg do not infringe SPC No. 95C0018 extended by the paediatric extension granted by the *INPI* on 6 July 2009,

- acknowledge that the conditions for the grant of the extension of SPC No. 95C0018, as set forth in Article 36 of Regulation (EC) No. 1901/2006, are not met,

- consequently, revoke the paediatric extension of SPC No. 95C0018,

- acknowledge that DU PONT DE NEMOURS used this now revoked title to stop the defendants from entering the Losartan market hereby acting wrongfully in such a way as to incur civil liability under Article 1382 of the French Civil Code,

- acknowledge that postponement of the opening of the Losartan and Losartan HCTZ market in France to 3 March 2010 was caused by DU PONT DE NEMOURS,

- acknowledge that MYLAN and QUALIMED's request for compensation for the damage caused is admissible,

- hold that Article 31 of the 19 July 1991 Act is applicable to the case of preliminary injunctions sought in intellectual property matters,

- order, jointly and severally, DU PONT DE NEMOURS and MERCK to pay them the sum of €230,360 as compensation for the damage resulting from the preliminary injunction restraining the marketing of their pharmaceutical products LOSARTAN HCTZ MYLAN and LOSARTAN HCTZ QUALIMED as well as the legal interests calculated as of the service of the summons on 8 March 2010,

- order them, jointly and severally, to pay MYLAN the sum of €3.37 million as compensation for the damage caused by the delay in the marketing of its pharmaceutical drug LOSARTAN, as well as the legal interests calculated as of the service of the summons on 8 March 2010,

- dismiss DU PONT DE NEMOURS and MERCK's claims based on Article 700 of the French Code of Civil Procedure,

- order them, jointly and severally, to pay MYLAN the sum of €100,000 on the basis of Article 700 of the French Code of Civil Procedure as well as the costs of

the proceedings, which will be recovered by their attorney-at-law,

- order the provisional enforcement of this judgment.

The closing order was handed down on 5 April 2012.

GROUNDS OF THE DECISION

- On the stay of the proceedings

In a decision dated 15 March 2011, the *Cour d'Appel* of PARIS affirmed the 12 February 2010 order in preliminary proceedings provisionally restraining the defendants from marketing pharmaceutical compositions using the characteristics of claims 1 to 5 of patent EP 0 253 310 and SPC No. 95C0018.

Explaining that they lodged an appeal on a point of law against this decision, MYLAN and QUALIMED request that the *Tribunal* stay the current proceedings pending the decision of the Commercial Chamber of the *Cour de Cassation*, claiming that the outcome of this appeal is likely to have a direct impact on the resolution of the dispute.

DU PONT DE NEMOURS and MERCK, which consider that this request is inadmissible since it was not made *in limine*, point out that it is based on the premise that the *Cour de Cassation* will refer the case to the ECJ for a preliminary ruling, a purely hypothetical situation in their opinion. Therefore, they argue that the request for a stay of the proceedings should be dismissed.

Contrary to what they indicate, a request for a stay of proceedings, which is not a procedural objection, should not be made before a defence as to the merits is filed, therefore the request must be held admissible.

However, it appears that if the stay were granted, it would unduly delay the proceedings since to await the outcome of an appeal on preliminary proceedings does not constitute a proper administration of justice.

Therefore, the request for a stay of the proceedings will be dismissed.

- On the subject-matter of the titles asserted by the claimants

**European patent EP 0 253 310*

As previously set out, DU PONT DE NEMOURS was the holder of patent EP 0 253 310 entitled "*Angiotensin II receptor blocking imidazoles"* relating to angiotensin II receptor antagonists (or blockers), a group of antihypertensive agents.

It is indicated that angiotensin II is one of the hormones which may cause hypertension, this hormone being derived from a precursor named blood plasma alpha 2-globulin, angiotensinogen produced and released in the blood circulation

mainly through the liver. The angiotensinogen is transformed into angiotensin I through the action of renin, an enzyme mainly produced by the kidneys. The enzyme renin, deprived of activity, is then converted into angiotensin II, physiologically active, through the action of a conversion enzyme found in the blood capillaries of the lungs and in the endothelium of the blood vessels in many parts of the body. Angiotensin II is a powerful vasopressor agent which constricts arteries and veins and increases blood pressure.

It is explained that the compounds of the invention according to the patent at issue allow a better treatment of hypertension by inhibiting the action of angiotensin II on its receptors in the target cells thus preventing the increase in blood pressure produced by this hormone-receptor interaction. They are also useful in the treatment of congestive heart failure.

The patent contains 45 claims. The compound at issue in these proceedings is Losartan, which is covered by claims 1 to 5 of the patent.

Claim 1 covers an antihypertensive derivative.

Claim 2 covers a derivative according to claim 1, having a different formula.

Claim 3 is a compound according to claim 2.

Claim 4 covers in particular the "*compounds of claims 1 to 3, selected from 2-Butyl-4-chloro-1-[(2'-(1H-tetrazol-5-yl)biphenyl-4yl)-methyl]-5-(hydroxymethyl)imidazole, or a pharmaceutically acceptable salt thereof*".

Claim 5 covers "*a pharmaceutical composition comprising a pharmaceutically suitable carrier and at least one compound of claims 1 to 4".*

It is added that the Losartan formula is a particular application of formula I of the compounds according to the said patent, it being specified that seven elements may be identified in this formula.

According to the claimants, no opposition was filed against this patent at the European Patent Office and no invalidity action was brought before the French Courts during the entire period of protection. They also argue that no generic drug containing Losartan was placed on the market by a generic manufacturer during the period of protection of the patent.

**SPC No. 95C0018*

The claimants explain that, on 16 June 1995, DU PONT DE NEMOURS filed an application for supplementary protection certificate (SPC) No. 95C0018 on the basis of marketing authorisations NL 20000 obtained in France on 15 February 1995 and NL 12209 obtained in Sweden on 2 September 1994, and that the SPC was granted on 17 October 1996. The SPC, which also covered Losartan, was to expire initially on 2 September 2009.

To extend the validity of the SPC by six months, DU PONT DE NEMOURS and MERCK submitted a paediatric investigation plan (PIP) to the Paediatric Committee set up under Regulation (EC) No. 1901/2006, which approved it on 18 February 2008.

In accordance with the Committee's proposal, the European Medicines Agency approved the PIP on 29 February 2008. The studies proposed in this PIP were conducted and completed.

DU PONT DE NEMOURS filed an application for a six-month extension of the SPC at issue in accordance with Article 36 of Regulation (EC) No. 1901/2006 of 12 December 2006 on medicinal products for paediatric use. This extension was granted by decision of the Director of the *INPI* on 6 July 2009.

Therefore, SPC No. 95C0018, which extended the protection of European patent EP 0 253 310 with specific regard to Losartan, expired on 2 March 2010. The claimants point out that, like the patent at issue, the SPC was never challenged during its entire period of protection.

- **<u>On the proceedings</u>**

MYLAN SAS, whose registered office is in LYON, belongs to the US group MYLAN. It specialises in the manufacturing and marketing of generic pharmaceutical products. QUALIMED SAS is one of its subsidiaries.

On 5 June 2009, the French Agency for the safety of health products (*Agence française de sécurité sanitaire des produits de santé*) granted MYLAN the authorisation to market its generic drugs LOSARTAN HCTZ MYLAN 50 mg and 100 mg. These drugs contain the two active ingredients Losartan and HCTZ.

On 2 February 2010, after exchanging registered letters in which MERCK warned MYLAN against marketing these drugs before 2 March 2010 and in which MYLAN argued that Losartan alone was different from its combination with hydrochlorothiazide (HCTZ), DU PONT DE NEMOURS and MERCK served a summons upon MYLAN and QUALIMED to appear in preliminary proceedings with an emergency motion to enjoin them, under penalty, from selling the pharmaceutical compositions reproducing the characteristics covered by claims 1 to 5 of patent EP 0 253 310 and SPC No. 95C0018.

As previously recalled, in an order dated 12 February 2010, the Judge in preliminary proceedings enjoined 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."*

In a decision dated 15 March 2011, the *Cour d'Appel* affirmed the challenged order but held that the penalty need not be ordered.

In the context of this dispute, DU PONT DE NEMOURS and MERCK request that the *Tribunal* "validate" the 12 February 2011 order affirmed by the decision dated 15 March 2011.

To oppose this request, MYLAN and QUALIMED challenge the validity of the extension granted to SPC No. 95C0018. Besides, they consider that the combination of LOSARTAN and HCTZ is different from LOSARTAN alone.

Each of these two points should be examined.

- On the validity of the extension of SPC No. 95C0018

As previously indicated, DU PONT DE NEMOURS filed an application for a six-month extension of SPC No. 95C0018 pursuant to Article 36 of Regulation (EC) No. 1901/2006 of 12 December 2006 on medicinal products for paediatric use. This extension was granted by decision of the Director of the *INPI* on 6 July 2009.

To challenge the validity of the extension, the defendants argue that Regulation (EC) No. 1901/2009, in particular Article 36, requires that the product at issue be authorised in all Member States. They add that, in their opinion, it was necessary to obtain the 27 marketing authorisations (MAs) at the time of filing the application for an extension and not after.

However, Article 36 of Regulation (EC) 1901/2006 on medicinal products for paediatric use provides in paragraph 3 that "*where the procedures laid down in Directive 2001/83/EC have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States.*"

Therefore, as rightly argued by the claimants, it does not result from the Article above that the product at issue should necessarily have been protected by a new MA relating specifically to paediatric formulas, since the product can be that upon which the initial SPC was based.

As a matter of fact, although it is correct that an extension, as the defendants point out, must be analysed as "*a reward granted to a laboratory having conducted paediatric clinical trials",* no text requires that authorisations for a specific paediatric use be granted.

Item 28 of that Regulation provides that "*because the 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"*, the only condition being that information

"*on use in paediatric populations"* be included, complies with this meaning, in accordance with the application.

Consequently, when identifying the authorisations existing in each country of the Union, the authorisations obtained for the initial product, namely Losartan, should be taken into account instead of the paediatric specification.

In addition, the defendants argue that the authorisations for the 27 Member States should have been obtained at the time of filing the application for an extension and not after.

They add that, in this respect, pursuant to the provisions laid down in Article R. 612-36 of the French Intellectual Property Code, "*only the correction of clerical errors discovered in the applications are permitted in the course of the prosecution".*

However, it results from the provisions laid down in Article 10(3) of Regulation (EC) No. 496/2009 concerning the supplementary protection certificate for medicinal products, Community legislation prevailing over national law, that "*where the application for a certificate does not meet the conditions laid down (...), the authority (...) shall ask the applicant to rectify the irregularity (...)",* which 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.

In this 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.

In addition, in its decision dated 22 January 2009 which was notified to the Member States on 26 January 2009, the European Commission decided that these Member States should amend the MAs for the medicinal products for paediatric use so as to authorise the pharmaceutical formula associated with a new dosage, within a time period which, under Article 34 § 3 of Directive 2001/83/EC, expired 30 days after its notification, that is, on 25 February 2009.

Yet the claimants justify having obtained decisions on the compliance of the studies with the PIP from the European Commission on 22 January 2009, from the Paediatric Committee on 6 February 2009 and from the Dutch authority on medicinal products on 13 February 2009, acting as a reference member and acknowledging the agreement by the other 26 national authorities, as well as decisions approving the paediatric MAs.

In addition, DU PONT DE NEMOURS indicates having obtained six-month extensions in all the Member States where it filed an application, which clearly demonstrates that it was unnecessary to obtain an MA in each of the 27 countries at the time of filing the applications for an extension, since these extensions would not have otherwise been obtained.

Therefore, it appears that the defendants fail to provide evidence of the alleged invalidity of the extension.

Consequently, since no irregularity was discovered in the asserted titles, no marketing of products reproducing the characteristics covered by these titles was possible up until 2 March 2010, the date upon which the validity of the SPC No. 95C0018 ended.

- On the use of the characteristics covered by the asserted titles

Pursuant to Article L. 613-3 of the French Intellectual Property Code "*the following shall be prohibited, save consent by the owner of the patent (…) manufacturing, offering, putting on the market or using a product which is the subject-matter of the patent, or importing or stocking a product for such purposes".*

On the basis of this Article, the claimants argue that the litigious pharmaceutical drugs, which the defendants were about to place on the market, infringed SPC No. 95C0018, its scope being clear, so that the imminent infringement was established.

On the contrary, MYLAN and QUALIMED claim that the reference MA, granted on 15 February 1995, covered Losartan only and that the combination of Losartan and HCTZ, composing the drug which they were about to launch, does not therefore constitute a potential infringement of the characteristics covered by the asserted titles.

However, Article 5 of Regulation (EC) No. 469/2009 concerning the supplementary protection certificate for medicinal products, provides 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"* whereas Article 4 of the Regulation provides that "*within the limits of the protection conferred by the basis 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".*

Pursuant to these Articles, it is not possible to conclude, as do the defendants, that only Losartan was covered by the protection at issue, and to consider that the combination of the two active ingredients is a different *product* from the ingredients composing it.

By using the term *product*, the European Community authorities have sought to protect, not the drug as such, but its active ingredient, whether alone or combined with other active ingredients, whether it contains other active ingredients or whether they contain it.

Since the active ingredient protected by the asserted titles was Losartan, it follows that all the drugs containing Losartan, alone or in combination with other active ingredients, could not be manufactured or marketed without violating the provisions laid down in Article L. 613-3 mentioned above.

Yet MYLAN and QUALIMED do not dispute that the drugs for which they respectively submitted an application for an MA contained Losartan, combined, as

explained, with hydrochlorothiazide.

Consequently, as the infringement alleged by the claimants was imminent, provisional measures restraining the marketing of the product granted in preliminary proceedings were justified until 2 March 2010, the date upon which the SPC at issue expired.

- On the validation and scope of the preliminary injunction

DU PONT DE NEMOURS and MERCK, besides requesting that the provisional measures be validated, consider that the Presiding Judge of the *Tribunal* wrongly limited the application of the preliminary injunction to the marketing of the product, whereas Article L. 613-3 mentioned above expressly prohibits "*making, offering, putting on the market, or using (…) importing or stocking a product".*

Therefore, they request that the *Tribunal* hold that the preliminary injunction should have been applied to these acts.

However, it does not result from the provisions laid down in Article L. 615-2 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, or even amend these measures, all the more since they are no longer relevant in this case.

The requests submitted in this respect will be dismissed.

- On the counterclaims

As the provisional measures restraining the marketing of the product are justified, the claims for compensation lodged by MYLAN and QUALIMED for the delay in marketing their drugs, as well as compensation for wrongful conduct, will be dismissed.

- On the other claims

MYLAN and QUALIMED, the losing parties, should be ordered to pay the costs which will be recovered pursuant to the provisions laid down in Article 699 of the French Code of Civil Procedure.

In addition, they must be ordered to pay DU PONT DE NEMOURS and MERCK, which had to incur irrecoverable costs to assert their rights, compensation pursuant to Article 700 of the French Code of Civil Procedure, which it is fair to set at the overall sum of €10,000, the additional claims lodged in this respect being dismissed.

Moreover, the circumstances of this case justify that the provisional enforcement of the decision be ordered, which is also compatible with the nature of the dispute.

ON THESE GROUNDS

The *Tribunal*, ruling publicly in the presence of both parties, by way of a judgment handed down in first instance and made available at the Court Clerk's office,

- DISMISSES the request for a stay of proceedings lodged by MYLAN and QUALIMED;

- HOLDS that the preliminary measures restraining the marketing of the pharmaceutical compositions, in particular LOSARTAN HCTZ MYLAN 50 mg and 100 mg reproducing the characteristics covered by claims 1, 2, 3, 4 and 5 of patent EP 0 253 310 and SPC No. 95C0018, before 2 March 2010, ordered in preliminary proceedings, were justified;

- DISMISSES all the claims lodged by MYLAN and QUALIMED;

- ORDERS, jointly and severally, MYLAN and QUALIMED to pay E.I. DU PONT DE NEMOURS & COMPANY and LABORATOIRES MERCK SHARP & DOHME-CHIBRET the overall sum of €10,000 pursuant to Article 700 of the French Civil Code Procedure;

- DISMISSES the other claims;

- ORDERS, jointly and severally, MYLAN and QUALIMED to pay the legal costs which will be recovered pursuant to the provisions laid down in Article 699 of the French Civil Procedure Code;

- ORDERS the provisional enforcement of this judgment.

Drafted and ordered in PARIS on 8 June 2012

The Court Clerk **The Presiding Judge**