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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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ORDER IN PRELIMINARY PROCEEDINGS
handed down on 28 January 2011

Docket No.
11/50892

BF/No.: 1

Summons of:
11 January 2011

by **Marie-Christine COURBOULAY, Vice-President** of the Paris *Tribunal de Grande Instance*, acting through delegation of authority from the President of the *Tribunal*,

assisted by **Stéphanie NABOT, Chief Court Clerk**

CLAIMANTS

NOVARTIS AG
Lichstrasse 35
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represented by Ms Laetitia BENARD, attorney-at-law, member of the PARIS Bar – courthouse box #J022

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represented by Ms Laetitia BENARD, attorney-at-law, member of the PARIS Bar – courthouse box #J022

DEFENDANTS

ACTAVIS GROUP PTC EHF
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represented by Mr Grégoire TRIET, attorney-at-law, member of the PARIS Bar - #T03

S.A.S. ACTAVIS FRANCE
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represented by Mr Grégoire TRIET, attorney-at-law, member of the PARIS Bar - #T03

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DISCUSSION

At the hearing of 24 January 2011 held publicly and presided by **Marie-Christine COURBOULAY**, Vice-President**,**

FACTS AND PARTIES' CLAIMS

The company governed by the laws of Switzerland, Novartis AG, is the holder of patent EP 0 443 983 entitled "*Acyl compounds*".

The European patent application was filed on 12 February 1991 by Ciba Geigy AG, claiming priority from two Swiss patent applications dated 19 February 1990 (CH 518/90) and 5 July 1990 (CH 2234/90). The mention of the grant of patent EP 0 443 983 was published on 28 February 1996 by the EPO. Patent EP 0 443 983 has been maintained in force by the regular payment of the annual fees and should expire on 12 February 2011.

Novartis AG replaces Cira[TN] Ceigy[TN] AG by virtue of a merger contract registered in the National Patent Register.

The subject-matter of the patent is a group of antihypertensive compounds, including valsartan, pharmaceutical preparations containing them and processes for the preparation of these compounds.

On 24 July 1997, Novartis AG filed an application for SPC No. 97 C 0050 on the basis of the marketing authorisation (MA) NL 22077 obtained in France on 21 March 1997 and on the basis of MA NL 36 983 obtained in Germany on 13 May 1996.

SPC No. 97 C 0050 was granted on 17 September 1999 and its grant was published in BOPI No. 99/39. It covers valsartan.

It has been maintained in force by the regular payment of the annual fees and should expire on 13 May 2011.

Novartis Pharma filed an application called "paediatric extension" pursuant to Article 36 of Regulation (EC) No. 1901/2006 dated 12 December 2006 relating to medicinal products for paediatric use.

By a decision dated 10 November 2010 published in BOPI No. 10/49 dated 10 December 2010, the Director of the INPI[TN] acceded to Novartis AG's claim.

The validity of SPC No. 97 C 0050 was thus extended until 13 November 2011.

Patent EP 0 443 983 has not been in any way disputed since its grant.

TN "Cira" should be read "Ciba".
TN "Ceigy" should be read "Geigy".
TN French patent office

Pursuant to a licence contract entered into on 5 July 2010 between Novartis AG and Novartis Pharma and registered in the National Patent Register, Novartis Pharma is the holder of an exclusive licence under the French designation of patent EP 0 443 983 and of an exclusive licence under SPC No. 97 C 0050. It is also the holder of different MAs for pharmaceutical products containing valsartan, which are marketed in France under the TAREG and COTAREG trademarks.

TAREG is indicated for the treatment of high blood pressure, heart failure and post-myocardial infarction. COTAREG is a medicinal product for human use, which combines two active ingredients, valsartan and a diuretic, hydrochlorothiazide "HCTZ", and which is indicated for the treatment of high blood pressure.

Actavis Group PTC EHF applied for the grant of a MA for pharmaceutical products "valsartan hydrochlorothiazide Actavis 80mg/12.5mg" and "valsartan hydrochlorothiazide Actavis 160mg/25mg"; it designated Actavis France as the exploiting company of these marketing authorisations.

These MAs were granted on 30 November 2009.

On 28 March 2010, Novartis' attorney-at-law informed Actavis Group PTC EHF and Actavis France of the existence of SPC No. 97 C 0050, which extended the companies' rights over valsartan until 13 May 2011.

On 23 July 2010, a new letter of formal notice not to infringe Novartis' rights was sent to each company Actavis.

On 29 October 2010, Novartis' attorney-at-law informed Actavis of the application for a paediatric extension and of the effect extension of SPC No. 97 C 0050 until 13 November 2011.

On 2 December 2010, a letter confirming the grant of the paediatric extension was sent to Actavis.

On 15 December 2010, Actavis' attorney-at-law replied that he was examining the information contained in Novartis' letters.

On 19 March 2010, Novartis' two generic drugs were registered in the *Répertoire des groupes génériques*[TN]. On 29 October 2010, with the objective of marketing their medicinal products, Novartis filed applications with the *Conseil Économique des Produits de Santé* to obtain the registration in the list of the reimbursable medicinal products.

[TN] French list of generic groups

It is under these conditions that Novartis AG and Novartis Pharma served a summons dated 11 January 2011 on Actavis Group PTC EHF and Actavis France to a preliminary hearing at set times, in order to:

Considering patent EP 0 443 983,

Considering SPC No. 97 C 0050, extended by its paediatric extension,

- enjoin the defendants from manufacturing, having manufactured, importing, offering for sale and selling, using and holding pharmaceutical preparations implementing the features covered by patent EP 0 443 983 and SPC No. 97 C 0050, under a €100 penalty per tablet manufactured, imported, offered for sale, sold, used or held in bulk or in another packaging form, as of the service date of the order to be handed down;

- order the publication of the entire decision to be handed down at Actavis' exclusive costs, in the form of a PDF document reproducing the entire decision and available by a visible hypertext link located on the home page of Actavis Group PTC EHF's and Actavis France's websites, whatever the address may be to have access to this website, the title of the hypertext link being in the appropriate language:

"*the President of the Paris* Tribunal de Grande Instance *ordered a preliminary injunction against Actavis Group PTC EHF and Actavis France, enjoining them from marketing in France pharmaceutical products comprising valsartan in infringement of Novartis' rights*"

in a font size of at least "20" for 6 months within a 8-day time limit as of the service of the decision to be handed down and under a penalty of 5,000 euros per delay day;

- order Actavis Group PTC EHF and Actavis France to pay 100,000 euros to Novartis AG and Novartis Pharma pursuant to Article 700 of the French Civil Procedure Code;

- recall that the decision is automatically enforceable;

- order Actavis Group PTC EHF and Actavis France to pay all the costs.

In support of their claims, they argued that the judge ruling in preliminary proceedings has jurisdiction since the threat of an infringement about to be committed against the claimants' rights is established. For that purpose, they quote the different actions for injunction in Germany and in Great Britain and all the steps made in France to market, as of May 2011, the pharmaceutical products including valsartan, for which the defendants obtained MAs and a reimbursement rate by the *CEPS*.

They argued that the patent and SPC No. 97 C 0050 covering valsartan can be asserted against any product containing valsartan, including a product containing valsartan and another product as a diuretic; that the infringement is appraised on similarities and not on differences.

They stated that a SPC was well an industrial property title and gave monopolistic rights over the product covered by this title.

They added that, first, pursuant to Article 5 of Regulation (EC) No. 1768/92 applicable to SPCs, the certificate confers the same rights as those conferred by the basic patent and that it is subject to the same limitations and obligations and, secondly, pursuant to the Article 4 of the same Regulation, the protection conferred by a SPC extends to the only 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 claim for security lodged by the defendants on the ground that they had financial means to pay the alleged possible damages.

At the hearing, on 24 February 2011, Actavis Group PTC EHF and Actavis France requested that the judge ruling in preliminary proceedings:

Considering Article L. 614-15 of the French Intellectual Property Code,

Considering Article L. 615-3 of the French Intellectual Property Code,

Considering Regulation (EC) No. 469/2009,

Considering paragraph 22 of the preamble of Directive 2004/48,

Mainly,
- hold that the conditions of Article L. 615-3 of the French Intellectual Property Code are not validly met;

- dismiss Novartis AG and Novartis Pharma S.A.S.'s all claims;

In the very alternative
- dismiss Novartis AG and Novartis Pharma S.A.S.'s claim for publication of the entire order to be handed down on the home page of Actavis' website for 6 months;

- order the prior payment by Novartis AG and Novartis Pharma S.A.S. of €15,000,000 (fifteen million euros) in the hands of an independent receiver to constitute the security provided for in Article L. 615-3 of the French Intellectual Property Code;

In any case
- order Novartis AG and Novartis Pharma S.A.S. to pay one hundred thousand euros (€100,000) to Actavis Group PTC EHF and Actavis France S.A.S. pursuant to Article 700 of the French Civil Procedure Code;

- order them to pay all the costs.

They did not dispute the validity of patent EP 0 443 983, of SPC No. 97 C 0050 and of the paediatric extension before the judge ruling in preliminary proceedings, specifying that these disputes could possibly be raised in proceedings on the merits.

However, they argued that the pharmaceutical products comprising valsartan alone, on the one hand, and valsartan combined with hydrochlorothiazide, on the other hand, constitute different products and that SPC No. 97 C 0050, which received a paediatric extension, only covers the use of valsartan alone; that the SPC does not confer the same rights to the holder as the patent; that this SPC and its paediatric extension, which are connected to a MA, cannot be asserted to prohibit medicinal products covered by another MA, resulting from a combination like valsartan and a diuretic for example.

They stated that only Regulation 469/2009 was applicable to the present facts and that Article 5 of the said Regulation should be read in association with Article 4 of the same text, which gives a solution opposite to the one alleged by the claimants.

THEREON

On the claims lodged before the judge ruling in preliminary proceedings:

Article L. 615-3 of the French Intellectual Property Code sets forth:
"*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 judge ruling in preliminary proceedings is referred to under the same conditions as those provided for in Article 809 of the French Civil Procedure Code, which allows him to rule on and to order any necessary preservative or compensatory measures, even if they are fiercely disputed, to prevent a damage about to be committed or to stop an obviously unlawful harmful act.

The defendants do not dispute that the introduction on the market of their pharmaceutical products "valsartan hydrochlorothiazide Actavis 80mg/12.5mg" and "valsartan hydrochlorothiazide Actavis 160mg/25mg" can constitute "*an infringement about to be committed against rights conferred by the title*", in particular, because, first, they were granted the necessary MAs and applied for a reimbursement rate for these pharmaceutical products with the *CEPS*, which is a prerequisite to a marketing on the French market, and, secondly, they dispute Novartis' rights over valsartan combined with hydrochlorothiazide.

However, Actavis disputes the likelihood of the infringement of Novartis' rights on the ground that the latter would not have any rights over valsartan combined with a HCTZ diuretic.

Therefore, the judge in preliminary proceedings should rule on the disputes raised before him against the claimed measures and these disputes can relate to the validity of the title itself; consequently, he has to appraise whether the dispute is grounded or not so as to prevent the use of preliminary proceedings to obtain serious injunction measures that would distort free competition on the basis of too weak a title.

Faced with a grounded dispute raised, he has to weigh up the opposing interests so as to observe a balance between the parties' rights, *i.e.*, between the seriousness of the damage about to be committed and its possible compensation and the seriousness of the requested injunction measure.

It is not disputed that the Regulation to be applied to the dispute is Regulation (EC) No. 469/2009 dated 6 May 2009 and more precisely Articles 4 and 5.

Article 5 of Regulation 469/2009 sets forth 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*".

Article 4 specifies 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 1 of this Regulation defines in particular the words "*medicinal product*", "*product*" and "*basic patent*".

The product is "*the active ingredient or combination of active ingredients of a medicinal product*". In the present case, the active ingredient is valsartan.

Thus, Article 4 can be read as follows:
"*Within the limits of the protection conferred by the basic patent* [patent EP 0 443 983], *the protection conferred by a certificate* [SPC No. 97 C 0050] *shall extend only to* [the active ingredient, *i.e.*, valsartan] *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.*"

No party disputes that these two articles should be read in the light of each other and that it should be said that SPC No. 97 C 0050 protects the only valsartan and no other active ingredient disclosed in patent EP 0 443 983.

Among all the acyl compounds disclosed in patent EP 0 443 983, only valsartan is protected as an active ingredient since it was the subject-matter of a MA to treat high blood pressure, heart failure and post-myocardial infarction.

Nor is it disputed that the paediatric extension was only granted for SPC No. 97 C 0050, which covers valsartan and whose validity was extended by 6 months until 13 November 2011.

The claimants argue that, accordingly, any use of valsartan in the pharmaceutical products that the defendants intend to market constitutes an infringement of their property rights.

The defendants reply that only valsartan is protected as an active ingredient and, therefore, no generic drug containing this only active ingredient can be marketed unless committing an infringement of the claimants' property rights, but valsartan, combined with another active ingredient, is protected by no property title so that the marketing of pharmaceutical products "valsartan hydrochlorothiazide Actavis 80 mg/12.5 mg" and "valsartan hydrochlorothiazide Actavis 160 mg/25 mg" can take place without risking the slightest infringement.

However, if Article 4 of the Regulation lays down limitations to the effects of the SPC, once they are defined, the SPC "*shall confer the same rights as conferred by the basic patent*".

Thus, SPC No. 97 C 0050 is valid for the only active ingredient valsartan and for the treatments specified in the MA, *i.e.*, for the treatment of high blood pressure, heart failure and post-myocardial infarction, and not for the other compounds of patent EP 0 443 983 or for other treatments than those specified in the MA.

But, once this SPC No. 97 C 0050 has been defined, the rights conferred to Novartis are the same as those conferred by the basic patent so that they can oppose any use of this active ingredient for treating high blood pressure, alone or in combination with another active ingredient.

Therefore, any marketing of a medicinal product containing valsartan as an active ingredient constitutes obviously an infringement since it infringes the rights the claimants possess over this active ingredient until 13 November 2011.

As a result, the obvious nature of the infringement, which can occur following the introduction of pharmaceutical products "valsartan hydrochlorothiazide Actavis 80mg/12.5mg" and "valsartan hydrochlorothiazide Actavis 160mg/25mg" on the market before 13 November 2011, is proved.

Consequently, the conditions of Article L. 615-3 of the French Intellectual Property Code are met and Novartis AG and Novartis Pharma's claims will be acceded to in the terms of the ordering part, specifying that only the marketing of pharmaceutical products "valsartan hydrochlorothiazide Actavis 80mg/12.5mg" and "valsartan hydrochlorothiazide Actavis 160mg/25mg" will be prohibited until 13 November 2011 since the manufacture, holding and import of generic drugs before the end of the protection period of the patent do not constitute an act of infringement.

The claim for a judicial publication on Actavis' website will not be acceded to as the irreparable nature of such a measure prohibits its pronouncement in preliminary proceedings.

On Actavis Group PTC EHF and Actavis France's counterclaims:

The defendants argue that it is up to the judge ruling on the merits of the case to rule on the validity of the claimants' titles and that the injunction measure, pronounced before the merits of the case are judged, necessarily causes them damage since they cannot market their pharmaceutical products on the scheduled date, in May 2011.

However, if a decision on the merits invalidates Novartis' titles or if it interprets differently Regulation 469/2009, the damages that would be pronounced following the loss of profit suffered by Actavis due to the non marketing of its pharmaceutical products, it is not shown that the recovery of these damages would meet any difficulty because, first, one of the claimants is a French company, which makes the recovery of the accounts receivable easier, including in case of forced enforcement, and, secondly, it is not alleged that Novartis will be unable to pay the requested sums considering the turnovers recorded by the latter.

Actavis Group PTC EHF and Actavis France's claim for interim damages will be dismissed.

On the further claims:

The conditions are met to grant 15,000 euros to Novartis AG and Novartis Pharma pursuant to Article 700 of the French Civil Procedure Code.

ON THESE GROUNDS

The *Tribunal*, ruling publicly, by making the order available at the Court Clerk's office, after due hearing of the parties and in first instance,

ENJOINS Actavis Group PTC EHF and Actavis France from offering for sale and selling, *i.e.*, from marketing pharmaceutical preparations and in particular pharmaceutical products "valsartan hydrochlorothiazide Actavis 80mg/12.5mg" and "valsartan hydrochlorothiazide Actavis 160mg/25mg", implementing the features covered in particular by patent EP 0 443 983 and by SPC No. 97 C 0050, **before 13 November 2011**, under a €100 penalty per tablet offered for sale and sold, in bulk or in another packaging form, the penalty taking effect as of the day of the order.

RESERVES the calculation of the final penalty to be ordered;

DISMISSES Novartis AG and Novartis Pharma's claim for a judicial publication on Actavis Group PTC EHF's and Actavis France's websites;

DISMISSES Actavis Group PTC EHF and Actavis France's all counterclaims;

ORDERS Actavis Group PTC EHF and Actavis France, jointly and severally, to pay the global sum of 15,000 euros to Novartis AG and Novartis Pharma pursuant to Article 700 of the French Civil Procedure Code;

RECALLS that this order is provisionally enforceable;

DISMISSES the parties' further claims;

ORDERS Actavis Group PTC EHF and Actavis France, jointly and severally, to pay the costs.

Ordered in Paris on **28 January 2011**

The Clerk,	The President,
Stéphanie NABOT	Marie-Christine COURBOULAY