FRENCH REPUBLIC

IN THE NAME OF THE FRENCH PEOPLE

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

Division 1 – Chamber 4

DECISION OF 16 SEPTEMBER 2011

(No. , 7 pages)

Docket Number: **11/02760**

Decision referred to the *Cour d'Appel*: order of 28 January 2011 – *Tribunal de Grande Instance* of Paris – Docket No. 11/50892

APPELLANTS

ACTAVIS FRANCE

represented by its President

Centre d'Affaires La Boursidière

92357 LE PLESSIS ROBINSON CEDEX

ACTAVIS GROUP PTC EHF

represented by its legal representative

a company governed by the laws of Iceland having its registered office at

Reykjavikurvegi 76-78,

220 HAFNARF JORDUR

ICELAND

represented by SCP DUBOSCQ et PELLERIN, *avoués* before the *Cour d'Appel*

assisted by Mr Grégoire TRIET, attorney-at-law, pleading on behalf of SCP GIDE LOYRETTE NOUEL, courthouse box: T05

and

RESPONDENTS

NOVARTIS AG

represented by its legal representatives

a company governed by the laws of Switzerland having its registered office at

Lichtstrasse 35

4056 BASEL

SWITZERLAND

SAS NOVARTIS PHARMA

represented by its legal representatives

2- 4 rue Lionel Terray

92500 RUEIL MALMAISON

represented by SCP MONIN ET D'AURIAC DE BRONS, *avoués* before the *Cour d'Appel*

assisted by Ms Laeticia BENARD, pleading on behalf of ALLEN OVERY LLP, attorney-at-law, member of the Paris Bar, courthouse box: J022

COMPOSITION OF THE COURT:

Pursuant to the provisions of Articles 786 and 910 of the French Code of Civil Procedure, the case was discussed on 30 June 2011, in public hearing, the attorneys-at-law not being opposed to it, before Mr Jacques LAYLAVOIX, Presiding Judge, and Ms Catherine BOUSCANT, Judge.

These judges gave an account of the oral pleadings during the deliberation of the Court, composed of:

Mr Jacques LAYLAVOIX, Presiding Judge

Ms Catherine BOUSCANT, Judge

Ms Martine TAILLANDIER-THOMAS, Judge

Court Clerk, during the discussion: Ms Lydie GIRIER-DUFOURNIER

DECISION:

- AFTER HEARING BOTH PARTIES

- the decision 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 Code of Civil Procedure.

- signed by Mr Jacques LAYLAVOIX, Presiding Judge and by Ms Véronique COUVET, Court Clerk to whom the minutes of this decision were handed by the signatory Judge.

Novartis AG, a company governed by the laws of Switzerland, is the holder of patent EP 0 443 983 entitled "*Acyl compounds*". It filed its application on 12 February 1991, and the patent published by the European Patent Office on 28 February 1996 remained in force until 12 February 2011, without having been the subject of a dispute since its grant. This patent relates to a group of antihypertensive compounds including valsartan which is marketed under the name "Tareg" and which, when combined with the diuretic hydrochlorothiazide - HCTZ, is marketed under the name "Cotareg".

On 17 September 1999, Novartis AG was granted the supplementary protection certificate "SPC" No. 97 C 0050 covering Valsartan and which expired on 13 May 2011. It was also granted a "paediatric extension" until 13 November 2011 so that the validity of SPC No. 97 C 0050 was extended until that date.

Novartis Pharma SAS is the holder of an exclusive licence for the French designation of European Patent EP 0 443 983 as well as of SPC No. 97 C 0050 and its paediatric extension.

Actavis Group PTC EHF is an Icelandic laboratory which markets generic drugs and which was granted, in France, on 20 November 2009, two marketing authorisations "MA" corresponding to the products "valsartan hydrochlorothiazide Actavis 80 mg / 12.5 mg" and "valsartan hydrochlorothiazide Actavis 160 mg / 25 mg" which are generic drugs of "Cotareg" and for which Actavis France SAS is referred to as the operating company, as well as the authorisation of being registered on a list of refundable proprietary drugs in December 2010.

As they became aware that Actavis intended to market the two above-mentioned generic drugs after the expiry of patent EP 983 which was due to occur on 12 February 2011, but before the expiry of SPC No. 97 0050, Novartis AG and Novartis Pharma (hereinafter referred to as Novartis), on 11 January 2011, summoned Actavis Group PTC EHF and Actavis France (hereinafter referred to as Actavis) to appear in preliminary proceedings with an emergency motion to be heard at very short notice for the purposes of enjoining them from committing various acts relating to the pharmaceutical compositions reproducing the characteristics covered by patent EP 0 443 983 and SPC No. 97 C 0050, pursuant to Article L 615-3 of the French Intellectual Property Code.

These are the conditions under which, by way of an order dated 28 January 2011, the Judge ruling in preliminary proceedings of the *Tribunal de Grande Instance* of Paris:

- enjoined Actavis Group PTC EHF and Actavis France from offering for sale and from selling, *i.e.* from marketing, pharmaceutical compositions and in particular the proprietary drugs "valsartan hydrochlorothiazide Actavis 80 mg / 12.5 mg" and "valsartan hydrochlorothiazide Actavis 160 mg / 25 mg" reproducing the characteristics covered in particular by patent EP 0 443 983 and by SPC No. 97 C 0050 before 13 November 2011, under a penalty of €100 per tablet offered for sale and sold in bulk or in any other form of packaging, the penalty taking effect as of the day the order was handed down;

- reserved the right to set the penalty to be ordered,

- dismissed Novartis AG and Novartis Pharma's request for a judicial publication on the website of Actavis Group PTC EHF and Actavis France,

- dismissed all Actavis Group PTC EHF and Actavis France's counterclaims,

- ordered Actavis Group PTC EHF and Actavis France, jointly and severally, to pay to Novartis AG and Novartis Pharma the overall sum of €15,000 pursuant to Article 700 of the French Code of Civil Procedure,

- dismissed the parties' other requests,

- ordered Actavis Group PTC EHF and Actavis France, jointly and severally, to bear the costs of the proceedings.

In their latest pleading served on 10 March 2011, Actavis Group PTC EHF and Actavis France SAS, appellants, mainly claiming that with regards to the law applicable to SPCs, neither the infringement of Novartis's rights nor the existence of the infringement is likely and that in any case, the requests for preliminary injunctions should be dismissed, request that the *Cour d'Appel*, considering Articles L. 614-15, L. 615-3 of the French Intellectual Property Code, EC Regulation No. 469 / 2009 and paragraph 22 of the preamble of Directive 2004/48:

on the main claim:

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

consequently,

- reverse the appealed order in that it enjoins Actavis Group PTC EHF and Actavis France SAS from offering for sale and selling the proprietary drugs "valsartan hydrochlorothiazide Actavis 80 mg / 12.5 mg" and "valsartan hydrochlorothiazide Actavis 160 mg / 25 mg" before 13 November 2011

on the alternative claim:

- order that a preliminary payment by Novartis AG and Novartis Pharma SAS of €15,000,000 be delivered into the care of an independent official 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 SAS to pay the sum of €100,000 to the appellants, pursuant to Article 700 of the French Code of Civil Procedure and to bear the costs of the proceedings.

In their latest pleading served on 15 April 2011, Novartis AG and Novartis Pharma SAS request that the Court, having regard to Article 5 of Regulation No. 469/2009, Articles L. 613-3, L. 615-1 and L. 615-3 of the French Intellectual Property Code, European patent EP 0 443 983 and supplementary protection certificate No. 97 C 0050 extended by its paediatric extension, affirm the appealed order in that it held a preliminary injunction from offering for sale and selling any pharmaceutical product containing valsartan and in particular the proprietary drugs "valsartan hydrochlorothiazide Actavis 80 mg / 12.5 mg" and "valsartan hydrochlorothiazide Actavis 160 mg / 25 mg" reproducing the characteristics covered by patent EP 0 443 983 and by the supplementary protection certificate No. 97 C 0050 extended by its paediatric extension before 13 November 2011, under a penalty of €100 per tablet offered for sale and sold in bulk or in any other form of packaging, the penalty taking effect as of the day the order is handed down; and adding thereto, that it also enjoin Actavis Group PTC EHF and Actavis France SAS from manufacturing, importing, using and holding for the previously mentioned purposes all pharmaceutical product containing valsartan and in particular the proprietary drugs "valsartan hydrochlorothiazide Actavis 80 mg / 12.5 mg" and "valsartan hydrochlorothiazide Actavis 160 mg / 25 mg" reproducing the characteristics covered in particular by patent EP 0 443 983 and by supplementary protection certificate No. 97 C 0050 extended by its paediatric extension before 13 November 2011, 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 decision is handed down, dismiss all the appellants' requests and order them to pay the sum of €100,000 pursuant to Article 700 of the French Code of Civil Procedure and to bear the costs of the proceedings.

Whereupon,

Considering that 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".

That Novartis should demonstrate that on the basis of the evidence it has and the property rights it owns, an infringement of its rights, by the manufacture and the sale of the two generic drugs by Actavis is likely or imminent and the Judge ruling in preliminary proceedings should determine the seriousness, or lack thereof, of a challenge;

Considering that in this case, the dispute mainly relates to the interpretation of "Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products", in particular Articles 4 and 5 thereof and with respect to the definitions given in Article 1 which are recalled hereunder;

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;

That the "product" means the active ingredient or combination of active ingredients of a medicinal product;

Considering that Article 4 of the regulation relates to the subject-matter 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";

That Article 5 relates to the effects of the certificate and 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";

Considering that the basic patent held by Novartis AG covers compounds among which valsartan appears in claim 26;

That Novartis AG filed an application for SPC No. 97 C 0050 on 24 July 2007 based on the marketing authorisation NL 22077 granted in France on 21 March 1997 and that the granted SPC published in the BOPI No. 99/39 covers Valsartan;

Considering that the Judge ruling in first instance, thereby following the arguments and the means developed by Novartis, considered that Article 4 could 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 SPC (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"; that it follows therefrom that since the SPC confers the same rights as those conferred by the basic patent, so that Novartis may oppose any use of the *active ingredient*, "*valsartan*", for treating high blood pressure, alone or in combination with another active ingredient, any marketing of a medicinal product containing valsartan as an active ingredient constituting an infringement;

That Novartis, in support of the first instance Judge's ground, adds that reasoning differently would lead to the misuse of the community regulation so that the grant of a SPC would not make it possible to oppose the marketing of a generic product merely containing additional ingredients in comparison to the reference drug which served as the basis for the grant of the SPC, like vitamins for example;

That Actavis, as far as it is concerned, considers that the first instance Judge mistook the notion of "product" for that of "active ingredient" and made an erroneous interpretation of the regulation;

Considering that the product as defined by the regulation is not restricted to an active ingredient and that the SPC pursuant to Article 4 does not protect the active ingredient but rather the product so that the SPC protects the valsartan product only;

That it follows therefrom that although the medicinal product valsartan + HCTZ does contain the active ingredient valsartan, it does not constitute a valsartan product according to the regulation but rather another product made of a combination of active ingredients;

That another interpretation could turn out to be contrary to the rule which prohibits the addition of SPCs mentioned in Article 3 of the regulation, providing that the SPC cannot cover another product and that there is only one SPC per product and per patentee, it being also noted that the HCTZ active ingredient cannot be considered as a simple additional ingredient like a vitamin;

That, therefore, it does not seem likely that the marketing of a medicinal product containing valsartan as an active ingredient would constitute an infringement and would infringe the rights held by Novartis on this active ingredient until 13 November 2011;

That the interpretation of the regulation suggested by Actavis and the challenge it raises against the measures requested by Novartis are serious and, contrary to the judgment rendered, deprive the alleged infringement of all obviousness;

That, consequently, the order should be reversed and Novartis's requests for a preliminary injunction should be dismissed.

Considering that Novartis has been unsuccessful and that its request based on Article 700 of the French Code of Civil Procedure will be dismissed and that it will be ordered, pursuant to this article, to pay €20,000 to Actavis and to bear the costs of the proceedings;

ON THESE GROUNDS

The *Cour d'Appel*, ruling publicly and in the presence of both parties,

Reverses the referred order,

Ruling again,

Dismisses the requests for injunctions lodged by Novartis AG and Novartis Pharma SAS,

Orders Novartis AG and Novartis Pharma SAS to pay the sum of €20,000 to Actavis Group PTC EHF and Actavis France pursuant to Article 700 of the French Code of Civil Procedure as well as the costs of the first instance and appeal proceedings which may be recovered pursuant to the provisions laid down in Article 699 of the French Code of Civil Procedure.

THE COURT CLERK **THE PRESIDING JUDGE**