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COUR DE CASSATION

Public hearing of **15 January 2013**

Quashing without remand

Mr ESPEL, Presiding Judge

Decision No. 21 F-D

Appeal No. A 11-26.632

F R E N C H R E P U B L I C

IN THE NAME OF THE FRENCH PEOPLE

THE *COUR DE CASSATION*, COMMERCIAL, FINANCIAL AND ECONOMIC CHAMBER handed down the following decision:

Ruling on the appeal on a point of law lodged by:

1°/ Novartis AG, a company governed by the laws of Switzerland, having its registered office at Lichtstrasse 35, 4056 Base (Switzerland)

2°/ Novartis Pharma SAS, having its registered office at 2-4 rue Lionel Terray, 92500 Rueil-Malmaison,

against the decision rendered on 16 September 2011 by the *cour d'appel de Paris* (Division 1, Chamber 4), in their dispute with:

1°/ Actavis France SAS, having its registered office at Centre d'affaires La Boursidière, 92357 Le Plessis-Robinson cedex,

2°/ Actavis Group PTC EHF, having its registered office at Reykjavikurvegi 76-78, 220 Hafnarfjörður (Iceland),

respondents in the appeal;

In support of their appeal, the appellants state the single annulment argument, annexed to this decision;

In light of the information communicated to the Public Prosecutor;

THE COURT, at the public hearing of 4 December 2012, composed of: Mr Espel, Presiding Judge, Ms Pezard, Reporting Judge, Mr Petit, Senior Judge, Ms Arnoux, Court Clerk;

Based on the report by Ms Pezard, Judge, on the observations of SCP Hémary and Thomas-Raquin, attorney-at-law representing Novartis AG and Novartis Pharma, of Mr Spinosi, attorney-at-law representing Actavis France and Actavis Group PTC EHF, on the opinion of Ms Batut, Advocate General, and after having deliberated in accordance with the law;

On the single argument:

In light of Articles 4 and 5 of Regulation (EC) No. 469/2009 of 6 May 2009 of the European Parliament and of the Council concerning the supplementary protection certificate for medicinal products, and Article L. 615-3 of the French Intellectual Property Code;

Whereas, according to the challenged decision, rendered in preliminary proceedings, that the company governed by the laws of Switzerland, Novartis AG, holder of European patent EP 0 443 983 in force until 12 February 2011, having as a subject-matter the active ingredient named valsartan and of the supplementary protection certificate (SPC) No. 97 C0050 expiring on 13 November 2011, and Novartis Pharma, holder of an exclusive licence under the French designation, (hereinafter referred collectively to as “*Novartis*”), having learned that the company governed by the laws of Iceland, Actavis Group, and Actavis France (hereinafter referred collectively to as “*Actavis*”) intended to market two generic medicinal products combining valsartan and another active ingredient, hydrochlorothiazide (HCTZ), served a summons upon these companies in order to obtain various injunctions in relation to the pharmaceutical compositions reproducing the characteristics covered by their patent and SPC;

Whereas, by the order of 9 February 2012 (C-442/11), the Court of Justice of the European Union declared that Articles 4 and 5 of Regulation (EC) No. 469/2009 must be interpreted as meaning that, when a product consisting of an active ingredient was protected by a basic patent and that the holder of this patent was able to rely on the protection conferred upon the product by this patent to oppose the marketing of a medicinal product containing this active ingredient in combination with one or more other active ingredients, an SPC granted for this very product may, subsequent to the expiry of the basic patent, allow its holder to oppose the marketing by a third party of a medicinal product containing the said product for a use of the product, as a medicinal product, which was authorized before the expiry of the said certificate;

Whereas, to reject Novartis' requests, the challenged decision maintains that the accused generic drug, comprising valsartan associated with HCTZ, does not constitute the same product as valsartan, which alone is covered by SPC No. 97C0050, and that therefore it is not realistic that any marketing of medicinal products containing valsartan as an active ingredient constitutes infringement and violates the rights to this active ingredient held by Novartis;

Whereas in reaching this decision without ascertaining whether or not the rights held by Novartis regarding their patent No. EP 0 443 983 allowed them to oppose the use of valsartan as a medicinal product in the accused generic drugs associating it with HCTZ, and whether or not, consequently, the latter infringed SPC No. 97C0050, which, like the basic patent, related to valsartan and conferred identical rights as the said patent on Novartis, the *cour d'appel* provided no legal grounds for its decision.

Whereas the appeal relating to the provisional measures which expired on 13 November 2011 has become void;

In light of Article 627 of the French Code of Civil Procedure;

ON THESE GROUNDS:

QUASHES AND RENDERS NULL AND VOID the decision, in all its provisions, rendered on 16 September 2011, between the parties, by the *cour d'appel de Paris*;

STATES that the appeal has become unfounded;

FINDS no grounds for referring the case back to the *cour d'appel*;

Orders Actavis to pay the costs;

Orders Actavis to equally bear the costs incurred in the proceedings before the judges ruling on the merits;

Considering Article 700 of the French Code of Civil Procedure, orders Actavis to pay Novartis the global sum of 2,500 euros and rejects their request;

States that at the behest of the Public Prosecutor of the *Cour de cassation*, this decision shall be transferred in order to be transcribed in the margin or following the quashed decision;

As drafted and decided by the *Cour de cassation*, commercial, financial and economic chamber, and pronounced by the Presiding Judge at this public hearing on the fifteenth of January two thousand and thirteen.