English translation by

VÉRON & ASSOCIÉS AVOCATS

COMM. JL

COUR DE CASSATION

Public hearing of **10 May 2011**

Stay of the proceedings

Ms FAVRE, Presiding Judge

Decision No. 446 F-D

Appeal No. W 10-13.882

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, has handed down the following decision:

Ruling on the appeal on points of law lodged by Daiichi Sankyo Company Limited, whose registered office is located at 5-1 Nihonbashi-Honcho 3-chrome Chuo-Ku, Tokyo (Japan),

against the decision handed down on 6 November 2009 by the *Cour d'Appel* of Paris (division 5, 2nd chamber), in the action opposing it to the Director General of the *Institut National de la Propriété Industrielle* (INPI)[1], domiciled 26 bis rue de Saint-Pétersbourg, 75008 Paris,

defendant in the appeal;

Considering the communication to the Public Prosecutor;

THE *COUR DE CASSATION,* at the public hearing of 29 March 2011, before: Ms Favre, Presiding Judge, Ms Mandel, Reporting Judge, Mr Petit, Senior Judge, Mr Mollard, Assistant Advocate General, Ms Molle-de Hédouville, Chamber Clerk;

[1] Translator's note: The French Industrial Property Office

Based on the report of Ms Mandel, Judge, on the observations of SCP Bénabent, attorney-at-law representing Daiichi Sankyo Company Limited, of Mr Bertrand, attorney-at-law representing the Director General of the *Institut National de la Propriété Industrielle*, on the opinion of Mr Mollard, Advocate General, and after having deliberated in accordance with the law;

On the sole annulment argument:

Considering the following:

According to the challenged decision (Paris, 6 November 2009), Daiichi Sankyo Company Limited filed supplementary protection certificate (SPC) application No. 06C0019 with the *Institut National de la Propriété Industrielle* on 12 June 2006, based on a European patent filed on 21 February 1992, granted on 25 April 2001, published under No. EP 0 503 785 entitled "1-Biphenylimidazole derivatives, their preparation and their therapeutic use" with a marketing authorisation granted in France on 8 February 2006 under No. CIS 66838901 for a proprietary medicine whose active ingredients are olmesartan medoxomil and hydrochlorothiazide; the Director General of the *INPI* rejected this application;

Daiichi Sankyo Company Limited criticizes the decision for dismissing its appeal for the reversal of the decision of the Director General of the *INPI* who rejected its application No. 06C0019, whereas, according to the argument:

1°/ pursuant to Articles 1(c) and 3(a) of EEC Regulation No. 1768/92 of 18 June 1992, the product "protected by a basic patent" is the product falling under the scope of protection of the patent; a combination of two active ingredients is "protected by a patent" pursuant to these articles when it is covered by the patent in any way; that the Cour d'Appel *violated Articles 1 and 3 of the above-mentioned EEC Regulation No. 1768/92 by requiring that the combination of active ingredients subject of the SPC application be "claimed as such" in the patent although it only had to find out, with regard to the patent specification in particular, whether this combination for a medicinal product intended for "the treatment of essential hypertension" was falling under the scope of patent No. 0 503 785, which precisely aims at protecting a series of compounds that "have valuable hypotensive activities and can be used for the treatment and prophylaxis of hypertension";*

2°/ pursuant to Articles 1 to 4 of EEC Regulation No. 1768/92 of 18 June 1992, the SPC is granted for a "medicinal product", i.e. for "any substance or combination of substances presented for treating or preventing diseases 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"; the Cour d'Appel *issued a ruling based on an inoperative ground, violating Articles 1 to 4 of the above-mentioned regulation by holding that olmesartan medoxomil was already the subject of MA No. NL 28292 of 6 August 2003 and of SPC No. 03C0037 granted on 11 February 2005 based on patent No. 0 503 785, although the medicinal product referred to in this MA and this SPC only had olmesartan medoxomil as an active ingredient and was covered by claims 1 to 4 of the patent, whereas the active ingredient of the medicinal product subject of MA No. CIS 6683901 was a combination of olmesartan medoxomil and hydrochlorothiazide and was covered by claim 5 of the patent, and therefore was not the same "medicinal product";*

By way of an order dated 5 November 2010, the Patents Court of England and Wales, ruling on an appeal against the decision of the UK Intellectual Property Office which had rejected a SPC application filed by Daiichi Sankyo company Limited equivalent to that filed in France under No. 06C0019 and also based on European patent No. 0 503 785, based on Article 267 of TFEU, requested that the CJEU issue a ruling on the four following questions (OJ of the European Union dated 26 February 2011, case C6/11):

1°/ *Regulation 469/2009 (the Regulation) (1) recognises amongst the other purposes identified in the recitals, the need for the grant of an SPC by each of the Member States of the Community to holders of national or European patents to be under the same conditions, as indicated in recitals 7 and 8. In the absence of Community harmonisation of patent law, what is meant in Article 3(a) of the Regulation by "the product is protected by a basic patent in force" and what are the criteria for deciding this?*

2°/ *In a case like the present one involving a medicinal product comprising more than one active ingredient, are there further or different criteria for determining whether or not "the product is protected by a basic patent" according to Art 3(a) of the Regulation and, if so, what are those further or different criteria?*

3°/ *In order for a combination of active ingredients cited in an authorisation for placing a medicinal product on the market to be the subject of an SPC, and having regard to the wording to Article 4 of the Regulation, is the condition that the product be "protected by a basic patent" within the meaning of Articles 1 and 3 of the Regulation satisfied if the product infringes the basic patent under national law?*

4°/ *In order for a combination of active ingredients cited in an authorisation for placing a medicinal product on the market to be the subject of an SPC, and having regard to the wording to Article 4 of the Regulation, does satisfaction of the condition that the product be "protected by a basic patent" within the meaning of Articles 1 and 3 of the Regulation depend upon whether the basic patent contains one (or more) claims which specifically mention a combination of (1) a class of compounds which includes one of the active ingredients in the said product and (2) a class of further active ingredients which may be unspecified but which includes the other active ingredient in the said product; or is it sufficient that the basic patent contains one (or more) claims which (1) claim a class of compounds which includes one of the active ingredients in the said product and (2) use specific language which as a matter of national law extends the scope of protection to include the presence of further other unspecified active ingredients including the other active ingredient in the said product?*

In addition, this same Court, by way of a decision dated 24 June 2010, requested that the CJEU rule on the 6 questions referred for a preliminary ruling relating to Articles 3(a) and 3(b) of Regulation No. 1768/92 and in particular on the question as to whether Article 3b) allows the grant of a SPC for one active ingredient or a combination of active ingredients when:

"*a) a basic patent in force protects the one active ingredient or the combination of active ingredients pursuant to Article 3(a) of the regulation on SPC and when*

b) a medicinal product containing one active ingredient or a combination of active ingredients, and one or more other active ingredients, is the subject of a valid authorisation granted in accordance with Directive 2001/83/EC or 2001/82/EC which is the first authorisation to place the active ingredient or the combination of active ingredients on the market?"

In the interest of the proper administration of justice and to contribute to ensuring a community harmonisation in the interpretation of Articles 1 to 4 of EEC Regulation No. 1768/92 applicable in this case, this appeal shall be stayed until the Court of Justice of the European Union has handed down a decision on the questions referred for a preliminary ruling by way of orders dated 5 November 2010 and 24 June 2010 by the Patents Court of England and Wales and registered under numbers C-6/11 and C-322/10;

ON THESE GROUNDS:

Stays the proceedings until the Court of Justice of the European Union has handed down a decision on the question referred for a

preliminary ruling by way of the orders dated 5 November 2010 (case C-6/11) and 24 June 2010 (case C-322/10) of the Patents Court of England and Wales;

Holds that a new hearing will be held before a limited bench (of three judges) on 13 December 2011;

Reserves the costs;

As drafted and decided by the *Cour de Cassation,* Commercial, Financial and Economic Chamber, and pronounced by the Presiding Judge at this public hearing of the tenth of May two thousand and eleven.