FRENCH REPUBLIC
IN THE NAME OF THE FRENCH PEOPLE

COUR D'APPEL OF PARIS

Section 5 – Chamber 2

DECISION OF 6 NOVEMBER 2009

(No. 279, 3 pages)

Docket number: **09/06530**

Decision referred to the *Cour d'Appel* of Paris: judgment of 13 February 2009 - *Institut National de la Propriété Industrielle* of PARIS – Docket No. 08/2845.jm

APPELLANT

DAIICHI SANKYO COMPANY LIMITED
successor in law to Sankyo Company Limited,
a company governed by the laws of Japan
whose registered office is located at 5-1 Nihonbashi Honcho 3-chrome,
Chuo-Ku, Tokyo
Japan

domiciled at the firm Fanet-Serra
avoués before the *Cour d'Appel* of Paris
5, quai Malaquais 75006 Paris
represented by the *SCP* Fanet-Serra, *avoués* before the *Cour d'Appel*
assisted by Mr Serge Binn, attorney-at-law, member of the Paris Bar, court house box P0515
pleading for the firm Lavoix Avocats, attorneys-at-law, members of the Paris Bar

RESPONDENT

The Director of the *INPI*
domiciled at 26 bis, rue de Saint-Pétersbourg 75008 Paris
represented by Ms Isabelle Hegedus, *chargée de mission*

COMPOSITION OF THE COURT:

The case was discussed on 1 October 2009, in public hearing, before the Court composed of:
Mr Alain Girardet, Presiding Judge; Ms Sophie Darbois, Judge;
Ms Dominique Saint-Schroeder, Judge, who deliberated

Court clerk, during the discussion: Ms Christelle Blaquières

Ministère Public[1] to whom the case was previously submitted and represented during the discussion by Ms Gizardin, *substitut du Procureur Général*[2], which made its opinion known

[1] The *Ministère Public* is composed of public servants representing the State and public interest in the judicial process. It has an advisory role and is independent from the parties. The *Ministère Public* is under the control of the Minister of Justice.

[2] The *procureur général* or his *substitut* (deputy) is a public servant acting for the *Ministère Public.*

DECISION: - after hearing both parties

- 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 Civil Procedure Code.

- signed by Mr Alain Girardet, Presiding Judge and Ms Christelle Blaquières, Court clerk to whom the minutes of this decision were handed by the signatory Judge.

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Having regard to the decision handed down on 3 December 2008 by way of which the Director General of the *Institut National de la Propriété Industrielle* rejected the application for a supplementary protection certificate for medicinal products No. 06C0019, made by DAIICHI SANKYO COMPANY LIMITED and based on the European patent filed on 21 February 1992 and 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 containing olmesartan medoxomil and hydrochlorothiazide as active ingredients.

Having regard to the appeal lodged on 6 March 2009 by DAIICHI SANKYO COMPANY LIMITED,

Having regard to the 6 April 2009 brief on the basis of which this company requests that the Court reverse the decision of the Director General of the *INPI*,

Having regard to the latter's observations filed on 5 June 2009 and aiming at the dismissal of the appeal.

The *Ministère Public's* observations having been heard.

WHEREUPON

Considering that the application for the supplementary protection certificate made by DAIICHI SANKYO COMPANY LIMITED is based on Council Regulation (EEC) No. 1768/92 of 18 June 1992, Article 3 of which defines the conditions for obtaining a certificate as follows:

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
a) the product is protected by a basic patent in force;
b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;
c) the product has not already been the subject of a certificate;
d) the authorisation referred to in (b) is the first authorisation to place the product on the market as a medicinal product.

Considering that pursuant to Article 1(b) of the said Regulation, the *product* means the active ingredient or the combination of active ingredients of a medicinal product; that it follows that a combination of active ingredients referred to in the MA may be the subject of a supplementary protection certificate provided that it is protected by the basic patent, which assumes that it is claimed as such.

Considering that, as DAIICHI SANKYO COMPANY LIMITED itself points it out, the European Court of Justice held, in its 16 September 1999 judgment, that in order to determine whether a product is protected by a basic patent, in the context of the application of the above-mentioned Regulation, and in particular, of Article 3(a) thereof,

reference must be made to the rules which govern the patent and the fact that the certificate cannot exceed the scope of the protection conferred by the basic patent;

In accordance with Article 69 of the Munich Convention, "*The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.*"

Considering that in this case, that basic patent No. 0 503 785 covers a family of 1-biphenyllimidazole derivatives as well as their pharmaceutically acceptable salts and esters;

Claim 5 adduced by DAIICHI SANKYO COMPANY LIMITED reads as follows:

Pharmaceutical composition for the treatment or prophylaxis of hypertension, which comprises mixing an anti-hypertensive agent with a pharmaceutically acceptable carrier or diluent, in which the anti-hypertensive agent is at least one compound of formula (I) or a pharmaceutically acceptable salt or ester thereof, as defined in any one of Claims 1 to 4.

Considering that it is not disputed that only olmesartan medoxomil is comprised in the family of 1-biphenyllimidazole-type derivatives because hydrochlorothiazide has a molecular structure which excludes it therefrom; furthermore, the proprietary medicine which has been the subject-matter of MA No. CIS 66838901 and placed on the market under the brand name Colmetec is presented as a combination of two molecules, an angiotensin II receptor antagonist (olmesartan medoxomil) and a diuretic (hydrochlorothiazide);

The combination of olmesartan medoxomil and hydrochlorothiazide is not protected by the basic patent because it is not claimed therein.

Considering that the appellant's developments on the foreign decisions about the granting of supplementary protection certificates are inoperative as they relate to distinct disputes; likewise, it is pointless to maintain that the combination at issue reproduces the characteristics of claim 5 since the question which is asked is whether this combination is protected by the patent and not whether it infringes it.

Considering, lastly, that olmesartan medoxomil, it alone being covered by the patent, has already been the subject of marketing authorisation No. NL 28292 of 6 August 2003 and of supplementary protection certificate No. 03C0037 granted on 11 February 2005 on the basis of the same patent;

It thus follows that the appeal lodged by DAIICHI SANKYO COMPANY LIMITED should be dismissed.

ON THESE GROUNDS

Dismisses the appeal lodged by DAIICHI SANKYO COMPANY LIMITED.

Holds that the Court clerk will notify the parties and the Director General of the *Institut National de la Propriété industrielle* of the decision.

THE COURT CLERK **THE PRESIDING JUDGE**