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COMM.

***COUR DE CASSATION***

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Public hearing of **23 November 2010**

Dismissal

Ms FAVRE, Presiding Judge

Decision No. 1194 F-D

Appeal No. S 09-15.668

F R E N C H   R E P U B L I C

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I N   T H E   N A M E   O F   T H E   F R E N C H   P E O P L E

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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 Institut Pasteur, a recognized foundation of public utility, whose registered office is located at 25-28 rue du Docteur Roux, 75015 Paris,

against the decision handed down on 4 March 2009 by the *Cour d'Appel* of Paris (4<sup>th</sup> chamber, section A), in the action opposing it to:

1°/ Chiron Healthcare, formerly known as Chiron Blood Testing SAS, a *société par actions simplifiée*, whose registered office is located at 10 rue de Chevreur, 92150 Suresnes,

2°/ Novartis Vaccines and Diagnostics, successor in law to Chinon<sup>1</sup> Healthcare, a *société par actions simplifiée*, domiciled at 10 rue de Chevreur, 92150 Suresnes,

3°/ Chiron Healthcare Ireland limited, a company governed by the laws of Ireland, whose registered office is located at United Drug House Belgarde Road, Dublin (Ireland),  
defendants in the appeal;

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<sup>1</sup> Translator's note: typing error in the French text, should read "Chiron".

The claimant puts forward, in support of its appeal, the five annulment arguments annexed to this decision;

Considering the communication to the Public Prosecutor;

THE *COUR DE CASSATION*, at the public hearing of 26 October 2010, before: Ms Favre, Presiding Judge, Ms Mandel, Reporting Judge, Mr Petit, Judge, Ms Arnoux, Chamber Clerk;

Based on the report of Ms Mandel, Judge, on the observations of SCP Barthélémy, Matuchansky et Vexliard, attorney-at-law representing Institut Pasteur, of SCP Hémerly et Thomas-Raquin, attorney-at-law representing Novartis Vaccines and Diagnostics and Chiron Healthcare Ireland Limited, on the opinion of Mr Bonnet, Advocate general, and after having deliberated in accordance with the law;

Considering that, according to the challenged decision (Paris, 4 March 2009), the holder of European patent No. 178978 filed on 17 September 1985 under the British priority of 19 September 1984, granted on 6 February 1991 and entitled "*Cloned DNA sequences, hybridizable with genomic RNA of lymphadenopathy-associated virus (LAV)*", Institut Pasteur lodged an action against Chiron Healthcare, whose successor in law is Novartis Vaccines and Diagnostics, and Chiron Healthcare Ireland Limited (hereinafter referred to as Chiron) criticising them for marketing HIV detection kits under the name Procleix which allegedly infringe upon claims 8 and 11 of this patent;

On the first annulment argument:

Considering the following:

Institut Pasteur criticises the appeal decision for dismissing its claims for infringement of claims 8 and 11 of patent No. 178978, whereas, according to the argument:

*1°/ Article 69 of the 5 October 1973 Munich Convention, which should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict and literal meaning of the wording used in the claims, is to be interpreted, according to Article 1 of the Protocol on the Interpretation of the said Article 69, as defining a position which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties; by retaining, to justify the claims' interpretation, the restrictive nature of the words used in the claims and thereby by confining itself to a literal reading thereof, whereas Institut Pasteur disputed such an interpretation, the Cour d'Appel violated Article 69 of the 5 October 1973 Munich Convention as explained by the Protocol on the*

*Interpretation published in French law by Decree No. 77-1151 of 27 September 1977, and Article L. 613-2 of the French Intellectual Property Code;*

*2°/ under Article 69 of the 5 October 1973 Munich Convention, the extent of the protection conferred by a European patent or a European patent application shall be determined by the claims, the description and drawings being used to interpret the claims; that according to Article 1 of the Protocol on the Interpretation of the said Article 69, this text shall be interpreted as defining a position which combines a fair protection for the patent holder with a reasonable degree of legal certainty for third parties; that by retaining the non-ambiguous nature of a claim to dismiss its interpretation for granting it a broad scope, even if, however, the possible ambiguity of a claim is not the only point to take into account to determine the protection conferred by the European patent, the Cour d'Appel based its decision on an ineffective ground and vitiated it by a lack of legal basis regarding Article 69 of the 5 October 1973 Munich Convention as explained by the Protocol on the Interpretation published in French law by Decree No. 77-1151 of 27 September 1977, and Article L. 613-2 of the French Intellectual Property Code;*

*3°/ under Article 69 of the 5 October 1973 Munich Convention, the extent of the protection conferred by a European patent or a European patent application shall be determined by the claims, the description and drawings being used to interpret the claims; that according to Article 1 of the Protocol on the Interpretation of the said Article 69, this text shall be interpreted as defining a position which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties; that by retaining, to justify the claims' limited scope, that Institut Pasteur would have been forced to limit the claims of the patent at issue during the examination and opposition procedure to distinguish itself from the prior art, whereas the possible amendments to a patent application during these proceedings do not have to be taken into consideration to determine the extent of the protection conferred by the final wording of the patent claims, the patent being sufficient in itself, the Cour d'Appel violated Article 69 of the 5 October 1973 Munich Convention as explained by the Protocol on the Interpretation published in French law by Decree No. 77-1151 of 27 September 1977, and Article L. 613-2 of the French Intellectual Property Code;*

*4°/ by contenting itself, to justify the claims' limited scope, to pointing out the amendment of the claims during the opposition procedure, reduced from 24 to 11, to be distinguished from the prior art, without explaining in which extent each of the claims asserted by Institut Pasteur against Chiron had been amended during the*

*opposition procedure, or the accurate meaning of the amendments possibly made, and the consequences regarding the prior art documents, the Cour d'Appel deprived its decision of a legal basis with respect to Article 69 of the 5 October 1973 Munich Convention as explained by the Protocol on the Interpretation published in French law by Decree No. 77-1151 of 27 September 1977, and Article L. 613-2 of the French Intellectual Property Code ;*

However, firstly, the *Cour d'Appel* did not content itself with a literal reading of the claims but gave specific grounds for its appraisal of the scope of claims 8 and 11 of patent No. 178978 with respect to the applicable texts by holding on its own grounds and on those adopted from the judgment, on the one hand, that claim 8 did not cover all diagnostic methods, regardless of the probe used, but that it was limited to a detection method involving the use of probes as defined in claims 1 to 6 of the patent, *i.e.* a probe formed from one of the cloned DNA fragments as defined by their restriction sites and corresponding to the retroviral genome of the LAV virus contained in clone  $\lambda$ -J19, and, on the other hand, that claim 11 protected only the specific nature of the purified RNA strand, namely its size from approximately 9.1 to 9.2 kb and its ability to hybridize with the cDNA contained in the clone  $\lambda$ -J19 and not any purified RNA sequence of the LAV virus (or HIV-1), regardless of its size; the first and second branches of the argument are conducted against superfluous grounds;

Secondly, although pursuant to Articles 69 of the Munich Convention in its version applicable to this case and L. 613-2 of the French Intellectual Property Code, the scope of the protection conferred by a patent is determined by the claims as amended following the opposition procedure and the drawings and the description shall be used to interpret the claims, the *Cour d'Appel*, by pointing out that the patent application had been initially filed with 24 claims but that, following the opposition procedure, it had been granted with 11 claims of a limited scope, simply appraised the scope of the claims in their final drafting; the *Cour d'Appel*, which did not have to proceed via the allegedly omitted research targeted by the fourth branch of the argument, legally justified its decision;

Accordingly, none of the argument's branches are founded;

On the second argument:

Considering the following:

Institut Pasteur criticises the appeal decision for dismissing its claims for infringement of claim 11 of patent No. 178978, whereas, according to the argument:

1°/ by contenting itself to holding that the patentee, which amended its claims to give them a limited scope, cannot, without harming the third parties' legal certainty, allege that the amendments were not necessary, that the limited claims would have the same scope as the broader initial ones and that the prior art documents grounding the amendments would not be relevant, without explaining the accurate meaning of the amendments made to claim 11 or the alleged consequence on the limitation of the scope of the said claim, the Cour d'Appel deprived its decision of a legal basis regarding Article 69 of the 5 October 1973 Munich Convention, as explained in the Protocol on its interpretation published in French law by Decree No. 77-1151 of 27 September 1977, and Article L. 613-2 of the French Intellectual Property Code;

2°/ under Article 69 of the 5 October 1973 Munich Convention, if the extent of the protection conferred by the European patent or the European patent application is determined by the claims, the description and drawings accompanying them are used to interpret them; according to Article 1 of the Protocol on the Interpretation of Article 69, this text should be interpreted as defining a position which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties; by retaining that the only characteristic distinguishing claim 11 was the specific nature of the claimed strand, namely its size of approximately 9.1 to 9.2 kb and its ability to hybridize with cDNA contained in clone  $\lambda$ -J19, without ascertaining, in the specific light of the description and drawings accompanying the patent, whether this claim should not be granted a broader scope, the Cour d'Appel deprived its decision of a legal basis regarding Article 69 of the 5 October 1973 Munich Convention, as explained in the Protocol on its interpretation published in French law by Decree No. 77-1151 of 27 September 1977, and Article L. 613-2 of the French Intellectual Property Code;

3°/ to form part of the state of the art and to be deprived of novelty, the invention should be disclosed, before the filing or priority date, in whole, in a single unquestioned prior art reference, disclosing the same elements constituting it in the same form, the same arrangement and the same operating mode for the same technical result; by retaining, to justify the limited scope attributed to claim 11, that the NIH's patent did anticipate Institut Pasteur's patent partially, whereas such a prior art document could not be taken into account failing to be a document constituting a complete anticipation of claim 11, the Cour d'Appel violated Articles 54, 69 and 138 of the 5 October 1973 Munich Convention, as explained in the Protocol on its interpretation published in French law by Decree No. 77-1151 of 27 September 1977, as well as Articles L. 611-11 and L. 613-2 of the French Intellectual Property Code;

4°/ *in any case, to form part of the state of the art and be deprived of novelty, the invention should be disclosed, before the filing or priority date, in a single unquestioned prior art reference disclosing the same elements constituting it in the same form, the same arrangement and the same operating mode for the same technical result; by retaining, to justify the limited scope attributed to claim 11, that the NIH's patent partially anticipated Institut Pasteur's patent, without explaining such a partial anticipation and in which extent it should lead to limit the scope of claim 11, the Cour d'Appel based its decision on an inaccurate ground depriving its decision of a legal basis regarding Articles 54, 69 and 138 of the 5 October 1973 Munich Convention, as explained in the Protocol on its interpretation published in French law by Decree No. 77-1151 of 27 September 1977, and regarding Articles L. 611-11 and L. 613-2 of the French Intellectual Property Code;*

5°/ *to form part of the state of the art and be deprived of novelty, the invention should be disclosed, before the filing date, in whole, in a single unquestioned prior art reference disclosing the same elements constituting it in the same form, the same arrangement and the same operating mode for the same technical result; by basing its decision of limiting the scope of claim 11 due to a prior disclosure constituted by the NIH's patent on the account that the suggestion in this prior art document of the presence of a pX gene has no importance in that it does not belong to the HIV genome, whereas the discovery that the pX gene does not belong to the HIV virus was made after the patent filing date, the Cour d'Appel violated, by misapplication, Articles L. 611-11 and L. 613-2 of the French Intellectual Property Code;*

However, firstly, the *Cour d'Appel* had no obligation to provide explanations on the amendments made during the granting procedure to determine the scope of claim 11;

Secondly, it does not result from Institut Pasteur's pleading before the *Cour d'Appel* that reference is made to the description or to the drawings of patent No. 178978 to define the scope that had to be conferred to claim 11; therefore, the argument is new and is both factual and legal;

Finally, as the *Cour d'Appel* held on adopted grounds that the Arya Gallo article published on 31 August 2004<sup>2</sup> disclosed the general method for purifying the HIV RNA from an AIDS patient's blood and taught that, according to this method, the isolated RNA sequences have a size of approximately 9 kb and that this purified RNA

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<sup>2</sup> Translator's note: error in the source text, the correct date is 31 August 1984.

comprises the entire R region at each end as well as the Poly A tail, its decision concerning the scope of claim 11 turns out to be justified by this sole ground;

Accordingly, as the second branch of the argument is inadmissible and the third, fourth and fifth branches are ineffective, the rest of the argument is not founded;

On the third argument:

Considering the following:

Institut Pasteur criticises the appeal decision for dismissing its claims for infringement of claim 8 of patent No. 178978, whereas, according to the argument:

*1°/ the extent of the protection conferred by the European patent or the European patent application is determined by the claims, the description and drawings being used to interpret the claims; by basing its decision on the patent granting procedure to justify the limited scope attributed to claim 8, whereas these proceedings had not to be taken into account to interpret this claim, only its final content and, possibly, the descriptions and drawings accompanying it, should be taken into account, the Cour d'Appel violated Article 69 of the 5 October 1973 Munich Convention, as explained in the Protocol on its interpretation published in French law by Decree No. 77-1151 of 27 September 1977, and Article L. 613-2 of the French Intellectual Property Code;*

*2°/ by basing its decision on the patent granting procedure to justify the limited scope attributed to claim 8, without explaining in which extent this claim had been amended, which had been the accurate sense of the amendments made and which had been the consequences thereof on the exact scope of claim 8, the Cour d'Appel deprived its decision of a legal basis regarding Article 69 of the 5 October 1973 Munich Convention, as explained in the Protocol on its interpretation published in French law by Decree No. 77-1151 of 27 September 1977, and Article L 613-2 of the French Intellectual Property Code;*

*3°/ by retaining, to justify the limited scope attributed to claim 8, that Institut Pasteur, during the examination and opposition procedure, had to amend this claim or the probe claim to which it refers to distinguish them from the fragment claims and thus be granted a larger protection, and to state afterwards that the paper published by the NIH's researchers, prior to the patent's priority date, already taught the detection of an infection due to HIV by the use of labelled probes, so that claim 8 could not relate to all diagnostic methods, the Cour d'Appel gave a ruling on contradicting*

grounds, equivalent to a lack of grounds, and accordingly violated Article 455 of the French Civil Procedure Code;

4°/ for determining the extent of the protection conferred by the European patent, due account is taken of any element equivalent to an element indicated in the claims; by contenting itself to pointing out, to justify the limited scope attributed to claim 8, that claim 8 could not relate to any diagnostic method regardless of the probe type used because of the amendments made therein, without however checking whether the probes used for the Chiron kits did not constitute simple variants or equivalents of elements constitutive of the product covered by claim 7, the *Cour d'Appel* deprived its decision of a legal basis regarding Article 69, paragraph 2, of the 5 October 1973 Munich Convention, as explained in the Protocol on its interpretation published in French law by Decree No. 77-1151 of 27 September 1977, and Article L. 613-2 of the French Intellectual Property Code;

However, firstly, the *Cour d'Appel*, which did not base its decision on the granting procedure to appraise the scope of claim 8 only pointed out that amendments had been made to it during this procedure and appraised it in its final version, did not have to proceed to the allegedly omitted research, targeted by the second branch of the argument, in order to determine this scope;

Secondly, in order to set aside Institut Pasteur's arguments according to which the process covered by claim 8 allegedly covers any diagnostic method regardless of the type of probe used, the decision points out, on its own grounds and on adopted grounds, that, on the one hand, this claim as amended requires using the probe, the subject-matter of claim 7, depending on claims 1 to 6 protecting cloned DNA fragments as defined by these claims and corresponding to the retroviral genome contained in clone  $\lambda$ -J19 and not any cloned DNA fragment of HIV, and, on the other hand, that the Arya Gallo article published before the patent's priority date already taught the detection of an HIV infection by using labelled probes; therefore, the *Cour d'Appel* did not contradict itself;

Finally, as the appraisal of a claim's scope constitutes a distinct examination from that relating to the appraisal of the infringement of a claim, the *Cour d'Appel*, which had no obligation to analyse the probes used for Chiron's kits, by considering that claim 8 cannot cover all diagnostic methods, regardless of the probe used, legally justified its decision;

Accordingly, none of the argument's branches are founded;



On the fourth argument:

Considering the following:

Institut Pasteur criticises the appeal decision for dismissing its claims for infringement of claim 11 of patent No. 178978, whereas, according to the argument:

*1°/ by confining itself to retaining, to dismiss the infringement, the length difference of the RNA isolated by Chiron's kits and the consideration that it contains a complete R sequence at each of its ends, without ascertaining whether, as argued by Institut Pasteur, the isolated product did not contain in whole the product covered by claim 11, the Cour d'Appel deprived its decision of a legal basis regarding Articles L. 613-3 and L. 613-4 of the French Intellectual Property Code, together with Article 69 of the 5 October 1973 Munich Convention, as explained in the Protocol on the Interpretation published in French law by Decree No. 77-1151 of 27 September 1977;*

*2°/ by stating, to dismiss the infringement of claim 11, that it is not denied that the RNA isolated by Chiron's kits has a size longer than 9.2 kb, whereas it itself had stated that the said kits allowed the isolation of a viral RNA as the one described in the Arya, Gallo article, which it had presented as having a size of approximately 9 kb, accordingly lower than 9.2 kb, the Cour d'Appel based its decision on contradictory grounds in violation of Article 455 of the French Civil Procedure Code;*

*3°/ by retaining, to dismiss the infringement of claim 11, that it was not proven at all that the implementation of the infringing kit allowed the particular isolation of the RNA fragment corresponding to the cDNA contained in  $\lambda$ -J19, whereas in its appeal pleading, Institut Pasteur precisely proved that the viral RNA captured with the infringing kit contained in whole the purified RNA corresponding to the cDNA contained in clone  $\lambda$ -J19, covered by claim 11, the Cour d'Appel distorted Institut Pasteur's pleading and violated the principle that the judge is not allowed to distort the documents of the case;*

However, the decision holds on its own grounds and on adopted grounds that claim 11 does not relate to all purified RNA sequences of the LAV virus regardless of size but covers the purified RNA of the LAV virus which has a size from 9.1 to 9.2 kb and which corresponds to the complementary DNA contained in  $\lambda$ -J19; it further holds that the kit for capturing viral RNA is not an essential element of this claim; it points out that there is no evidence that Chiron's kit would permit one to isolate the RNA fragment corresponding to the complementary DNA contained in  $\lambda$ -J19 and that the RNA isolated using this kit would contain a complete R sequence at each of its ends;

having thus pointed out that the isolation of an RNA fragment corresponding to the complementary DNA contained in  $\lambda$ -J19 constitutes an essential element of the invention and that this isolation could not be performed with the accused kit, the *Cour d'Appel* was able, without contradicting itself and leaving the ground criticised by the second branch of the argument aside, to issue such ruling; the argument is not founded;

And on the fifth argument:

Considering the following:

Institut Pasteur criticises the appeal for dismissing its claims for infringement of claim 8 of patent No. 178978, whereas, according to the argument, *the infringement by equivalence presupposes that the patented means does not fulfil a known function; by limiting itself with retaining, regarding the appraisal of the infringement of claim 8, that the doctrine of equivalents could not apply in the present case as claim 8 does not cover the general means of hybridization, but the specific means of hybridization of the viral RNA with a probe composed of a DNA fragment corresponding to the genome contained in clone  $\lambda$ -J19, without however noticing that the means so covered by claim 8 fulfilled a function actually known at the claimed priority date, the Cour d'Appel deprived its decision of a legal basis regarding Articles L. 613-3 and L. 613-4 of the French Intellectual Property Code, together with Article 69 of the 5 October 1973 Munich Convention, as explained in the Protocol on the Interpretation published in French law by Decree No. 77-1151 of 27 September 1977;*

However, the decision holds, on adopted grounds, that the DNA/RNA hybridization method for detecting HIV was already known at the date of the claimed priority, in particular, the Scotto *et al.* article of 1983 describes the use of the hybridization method for detecting DNA of hepatitis B virus in serum; the Arya Gallo article describes the application of this method for the detection of the AIDS virus by the use of probes composed of labelled cloned DNA fragments; it infers therefrom that as the means of hybridization of DNA/RNA for detecting HIV was known, claim 8 did not cover the general means of hybridization but rather a specific means of hybridization of viral RNA with a probe composed of a DNA fragment corresponding to the genome contained in clone  $\lambda$ -J19; the *Cour d'Appel* legally justified its decision; the argument is not founded;

ON THESE GROUNDS:

DISMISSES the appeal;

Orders Institut Pasteur to pay the costs;

Considering Article 700 of the French Code of Civil Procedure, orders it to pay to Chiron Healthcare Ireland limited and Novartis Vaccines and Diagnostics the total sum of €2,500, and dismisses its claim;

As drafted and decided by the *Cour de Cassation*, Commercial, Financial and Economic Chamber, and pronounced by the Presiding Judge at this oral hearing of the twenty-third of November two thousand and ten.