English translation by

VÉRON & ASSOCIÉS AVOCATS

T R I B U N A L
D E GRANDE
I N S T A N C E
O F P A R I S

■

3rd Chamber
2nd Section

Docket No.: **08/08679**

Summons dated:
24 June 2005

JUDGMENT
issued on 28 May 2010

CLAIMANT

INSTITUT PASTEUR
25-28 rue du Docteur Roux
75015 PARIS

represented by Ms Marina COUSTE, attorney-at-law, member of the PARIS Bar, courthouse box L295

DEFENDANT

SIEMENS HEALTHCARE DIAGNOSTICS, formerly called BAYER DIAGNOSTICS, represented by Mr Juan Manuel Martin DUAIGUES
9 Boulevard Finot
93200 SAINT DENIS

represented by Mr Pierre VERON, attorney-at-law, member of the PARIS Bar, courthouse box P24, and by Mr Thomas BOUVET, attorney-at-law, member of the LYON Bar

COMPOSITION OF THE COURT DURING THE DISCUSSION

Véronique RENARD, Vice Presiding Judge
Eric HALPHEN, Vice Presiding Judge
Sophie CANAS, Judge,

Enforceable copies issued on: 31/05/2010

COMPOSITION OF THE COURT DURING THE PRONOUNCEMENT OF THE DECISION

Véronique RENARD, Vice Presiding Judge
Sophie CANAS, Judge, *who signed the decision*
Anne CHAPLY, Judge

assisted by Jeanine ROSTAL, acting as court clerk, *who signed the decision*

DISCUSSION

At the hearing of 12 March 2010
held in open court

JUDGMENT

Pronounced by delivery of the decision to the Court Clerk's office
After due hearing of the parties
in first instance

FACTS, PROCEEDINGS AND PARTIES' CLAIMS

INSTITUT PASTEUR, a foundation recognised to be of public utility, is the holder of European patent No. 0 178 978 filed on 17 September 1985, claiming priority from GB patent No. 8423659 dated 19 September 1984, granted on 6 February 1991 and entitled "*Cloned DNA sequences, hybridizable with genomic RNA of "lymphadenopathy-associated virus (LAV)"*.

The French *société par actions simplifiée* called BAYER DIAGNOSTICS has marketed, since 2003 in France, kits under the name *Versant HIV-1 RNA 3.0 Assay (bDNA)* for the quantitative diagnosis of the *virus d'immunodéficience humaine* (VIH or, in English HIV for "*human immunodeficiency virus"*) causing acquired immune deficiency syndrome (AIDS) in man.

Considering that these detection kits as well as the included reagents implement the features of the invention described in patent EP 0 178 978, and after having carried out a duly authorised *saisie-contrefaçon* on 9 June 2005 at BAYER DIAGNOSTICS's registered office located in PUTEAUX (92), and in the premises of the BICHAT-CLAUDE BERNARD Hospital located in PARIS 18e, INSTITUT PASTEUR, in accordance with the 24 June 2005 summons, sued BAYER DIAGNOSTICS for infringement of claims 5, 7, 8 and 11 of European patent No. 0 178 978 in order to obtain, in addition to measures of injunction, confiscation for destruction and publication, as well as the production of accounting documents, the payment of damages and compensation with respect to Article 700 of the French Civil Procedure Code, all these measures enjoying provisional enforcement.

The case was successively removed from the register by orders of 4 November 2005 and 9 March 2007 and lastly re-entered for trial at the scheduling conference held on 16 October 2008.

In its recapitulative pleading notified on 3 September 2009, to which express reference is made, INSTITUT PASTEUR requests that the *Tribunal:*
As a main request,
- dismiss the claims for procedural issues and pleas lodged by Bayer Diagnostics (now Siemens Healthcare Diagnostics),
- hold that European patent No. 173 529, called *Gallo*, and Dr Arya's article cannot be cited against European patent No. 178 978 because they were abusively disclosed,
- dismiss all the claims, purposes and conclusions raised by Bayer Diagnostics (now Siemens Healthcare Diagnostics),
- hold that Bayer Diagnostics (now Siemens Healthcare Diagnostics) has been liable for infringement of European patent EP 178 978 B2 by the importation, use, holding, offer for sale and sale of reagents and kits, and by the delivery or offer for sale to third parties of the means necessary for purifying the HIV-1 RNA and for implementing the diagnostic method, which in particular infringe claims 5, 6, 7, 8 and 11 of the French designation of European patent 178 978 B2,
in the alternative,
- appoint an expert at the *Tribunal*'s discretion with the mission of defining whether the RNA of the AIDS virus purified with the *Versant® HIV-1 RNA 3.0 Assay (bDNA)* necessarily corresponds to the whole genomic RNA specific to the AIDS virus as defined, for the first time, in claim 11 of the patent at issue,
mainly and in the alternative,
- order Bayer Diagnostics (now Siemens Healthcare Diagnostics) to compensate for the damage caused to Institut Pasteur and to immediately pay it a €2 million advance,
- appoint an expert at the *Tribunal*'s discretion with the mission of assessing the damage suffered by Institut Pasteur by receiving all pertinent information allowing him to complete the said calculation, including the turnover recorded with the apparatus dedicated to the use of the infringing products, and enjoin Bayer Diagnostics (now Siemens Healthcare Diagnostics) to provide all certified accounts on the turnovers it has recorded since the first sale of these products in France,
- authorise Institut Pasteur to publish the judgment to be issued in ten newspapers or reviews of its choice, at the expense of Bayer Diagnostics (now Siemens Healthcare Diagnostics) and not exceeding 20,000 euros per insertion, this being considered as supplementary damages,
- hold that the pronounced orders will relate to all the infringement acts committed until the day of the final decision that will be issued on this claim or until the patents' expiry,
- because of urgency of the situation, order the provisional enforcement of the judgment to be issued notwithstanding an appeal and without the obligation to provide security,

- order Bayer Diagnostics (now Siemens Healthcare Diagnostics) to pay 200,000 euros to Institut Pasteur pursuant to Article 700 of the French Civil Procedure Code and to pay all the costs, which will be collected by Ms Marina COUSTE, attorney-at-law acting with authority, under the conditions provided for in Article 699 of the French Civil Procedure Code.

In the last pleading dated 26 November 2009, to which reference is also made, SIEMENS HEALTHCARE DIAGNOSTICS, which was formerly called BAYER DIAGNOSTICS and will be called SIEMENS hereafter, requests that the *Tribunal*:
- hold that claims 5, 6 and 7 of patent No. 0 178 978 do not have the broad scope that INSTITUT PASTEUR attributes to them, but that they only cover the literally claimed fragments, which are characterised by their ends, their size and their location on the viral genome as contained in clone λ-J19,
- hold that claim 8 does not have the scope that INSTITUT PASTEUR attributes to it, but that it only covers a detection method using a probe according to claim 7, therefore a probe composed of one of the fragments according to claims 1 to 6,
- hold that claim 11 of patent No. 0 178 978 cannot be interpreted as alleged by INSTITUT PASTEUR, that is to cover any purified RNA of the LAV virus, whose size is longer than 9.2 kb and regardless of knowing whether it corresponds to the complementary DNA contained in clone λ-J19,
- therefore, hold that by importing and marketing the quantitation kit, SIEMENS is not liable for direct infringement of claims 5, 6 and 7 or for contributory infringement of claims 8 and 11 of patent No. 0 178 978,
- in the alternative, should claims 5, 6, 7, 8 and 11 be interpreted as INSTITUT PASTEUR alleges, hold that these claims are invalid for insufficient disclosure or for lack of novelty,
in any case,
- dismiss INSTITUT PASTEUR's claims for infringement of patent No. 0 178 978 lodged against SIEMENS,
- order INSTITUT PASTEUR to pay 200,000 euros to SIEMENS as compensation for the damage suffered from the abusive nature of these proceedings,
- order INSTITUT PASTEUR to pay 400,000 euros to SIEMENS pursuant to Article 700 of the French Civil Procedure Code and to pay all the costs, which will be collected in accordance with Article 699 of the French Civil Procedure Code.

The closing order was issued on 28 January 2010.

GROUNDS OF THE DECISION

By way of an introduction, one should point out that SIEMENS no longer raises, in its latest pleading, the invalidity of the *saisie-contrefaçon* reports drafted on 9 June 2005; consequently the arguments INSTITUT PASTEUR devotes to this issue are without object.

- On the historical and scientific context

Prior to the examination of the subject-matter of the invention and in order to better appraise its scope, one should recall the history of the research on the virus causing AIDS, a new disease appearing in 1980 around the world, and more particularly in the United States, and which was officially named "AIDS" as of 27 July 1982;

From the early 1980s onwards, research was mainly conducted in parallel by two teams: a French team headed by Professor MONTAGNIER within the INSTITUT PASTEUR and an American team headed by Professor GALLO, who himself is at the origin of the discovery of the first human retrovirus in 1980, called human T-cell lymphotropic virus type I or HTLV-1, within the National Institutes of Health (NIH), an entity depending on the United States Department of Health and Human Services;

Now, it is established that, although the NIH's team officially announced in 1984 having isolated the virus causing AIDS, named HTLV-III because, according to it, it belonged to the oncovirus HTLV family (for Human T-cell Lymphotropic Virus), in reality it is Professor MONTAGNIER's team which, for the first time described the AIDS virus in an article published in magazine *Science* on 20 May 1983; the virus was called LAV (for Lymphadenopathy-Associated Virus) because the team rightly thought that it belonged to the lentivirus family;

The authorship of this discovery was at the origin of a very important litigation between Professors GALLO and MONTAGNIER, which ended in 1987 with the conclusion of an agreement between INSTITUT PASTEUR and the United States Department of Health and Human Services (HHS) and with the publication of a common press release by both institutes recalling the chronology of each person's respective contributions and in particular attributing to the French team the identification in May 2003 of the LAV retrovirus, which is different from HTLVs;

After having identified the virus causing AIDS, the research, from 1984 onwards, related to the characterisation and sequencing of the genome of the HTLV-III, LAV and ARV viruses (ARV for AIDS-Associated Retrovirus, isolated by Professor LEVY of the University of San Francisco); in January-February 1985, the publication of the nucleotide sequences forming the viral RNA (for RiboNucleic Acid) – which is mainly composed by the *gag, pol* and *env* genes – confirmed that the viruses studied by each team were identical;

The single acronym HIV for Human Immunodeficiency Virus (in French VIH for *Virus d'Immunodéficience Humaine*) was suggested by the International Committee of Taxonomy of Viruses in 1986 and permanently replaced the words LAV and HTLV-III, being specified that a second virus causing AIDS – called HIV-2 – was disclosed in 1985, but only the aforementioned virus, which has since been called HIV-1, is at issue in this dispute;

In addition to immunological assays detecting the presence of proteins synthesised by the viral RNA or the presence of specific antibodies, knowledge of the HIV genome made possible the development of genetic assays enabling the detection of the viral genome itself by means of probes composed of DNA or RNA strands, which are complementary to and specific to the target gene whose presence is sought, and accordingly enabling the diagnosis of the disease early on, which is essential in particular for securing blood donations used during a blood transfusion;

Both the patented invention asserted in the present case and the allegedly infringing *Versant HIV-1 RNA 3.0 Assay (bDNA)* kit for quantitative dosing relate to this second category of assays.

- On the subject-matter of European patent No. 0 178 978

European patent No. 0 178 978, filed on 17 September 1985, claiming British priority of 19 September 1984 and granted on 6 February 1991, was opposed before the European Patent Office and was maintained with amended claims by a decision of the Board of Appeal dated 18 November 1999;

The invention entitled "*Cloned DNA sequences, hybridizable with genomic RNA of "lymphadenopathy-associated virus (LAV)"* relates to cloned DNA sequences hybridizable with genomic RNA and DNA of the lymphadenopathy virus (LAV) – today called HIV as said above –, to a process for preparing the said sequences and to their uses, more particularly to stable probes comprising a DNA sequence, which can be used for detecting the LAV virus or related viruses or DNA proviruses in any medium, particularly in biological samples containing any one of these;

The descriptive part recalls that the detection methods available to date are based on the recognition of viral proteins and that such a method is described in European patent application EP-A-138 667 entitled "*Antigènes, moyens et méthode pour le diagnostic de lymphadénopathie et du syndrome d'immunodépression acquise"* (in English, "*Antigens, means and methods for the diagnosis of lymphadenopathy and acquired immune deficiency syndrome*"), filed on 14 September 1984 and claiming priority from British patent application No. 83 24 800 filed on 15 September 1983;

It is stated that the aim of the invention is to provide new means that would not only be also useful for the detection of LAV or related viruses, but would also have more versatility, particularly in detecting specific parts of the genomic DNA of these viruses, whose expression products are not always detectable by immunological methods;

For this purpose, the patent is composed of eleven claims, which are worded as follows:

"*1. A cloned DNA which contains a DNA corresponding to the LAV retroviral genome contained in λJ19 (CNCM I-338), said cloned DNA including LTR elements U3, R and U5 of said retroviral genome.*

2. The DNA of claim 1 which is a cDNA.

3. A cloned DNA which contains a DNA which consists:
either of a 3 terminal fragment of the DNA contained in λJ19 (CNCM I-338) including the R and U3 regions of the 3' LTR, and which has up t0 2.5 kb which contains the following restriction sites in the respective orders which follow (from the 3' end to the 5' end):
1) either Hind III, Sac I, Bgl II,
2) or Hind III, Sac I, Bgl II, Bgl II, Kpn I,
3) or Hind III, Sac I, Bgl II, Bgl II, Kpn I, Xho I, Bam HI, Hind III, Bgl II.

4. A cloned DNA fragment whose sequence corresponds to the part of the DNA of λJ19, which extends from approximately Kpn I (6100) to approximately Bam HI (8150) thereof.

5. A cloned DNA fragment whose sequence corresponds to the part of the DNA of λJ19, which extends from approximately Kpn I (3500) to approximately Bgl II (6500) thereof.

6. A cloned DNA fragment whose sequence corresponds to the part of the DNA of λJ19, which extends from approximately Pst I (800) to approximately Kpn I (3500) thereof.

7. A probe for the in vitro detection of LAV which consists of a DNA according to any of claims 1 to 6.

8. A method for the in vitro detection of viral infection due to the LAV viruses which comprises contacting a biological sample originating from a person to be diagnosed for LAV infection and containing RNA in a form suitable for hybridization with the probe of claim 7 under hybridizing conditions and detecting the hybridized probe.

9. A vector, particularly a plasmid, for the transformation of procaryotic or eucaryotic cells which contains an insert consisting of the DNA of any of claims 1 to 6.

10. A microorganism, eucaryotic or procaryotic cell which is transformed by a vector according to claim 9.

11. The purified RNA of LAV virus which has a size from 9.1 to 9.2 kb and which corresponds to the cDNA contained in λJ19 (CNCM I-338)."

In this instance, INSTITUT PASTEUR only relies on claims 5, 6, 7, 8 and 11 of the patent.

- On the scope of claims 5, 6, 7, 8 and 11 of European patent No. 0 178 978

INSTITUT PASTEUR maintains that, for the first time, patent No. 0 178 978 allowed the detection of very small quantities of virus, the AIDS-causing agent, within very brief periods of time, which has been decisive in halting the risks of contamination and favouring the establishment of an anti-retroviral treatment and the follow-up of its effectiveness; accordingly, the *Tribunal* should take into account the pioneering nature of this invention when it appraises the facts of the present case;

More precisely it argues that claim 8 protects a new general means for detecting and quantitating the AIDS virus by hybridizing DNA probes labelled with the viral RNA, these probes being defined in claim 7, which refers to claims 1 to 6 – reproduced above – and in particular to claims 5 and 6, which identify the region of the *pol* gene specific to the virus;

Therefore, it considers that the patent covers all DNA probes, even though they may not be expressly disclosed and notwithstanding all the forms of variations or improvement, provided only that they are hybridizable with the RNA of the AIDS virus to guarantee detection;

According to its reasoning, INSTITUT PASTEUR also considers that claim 11 of the asserted patent protects the purified RNA of the virus causing AIDS in its entirety, the latter corresponding to the complementary DNA contained in clone λ-J19 and not to a specific fragment isolated at random;

SIEMENS opposes in substance the fact that the claimant tries to give claims 5, 6, 7, 8 and 11 of its patent the scope of previous claims that it was obliged to renounce during the grant and opposition proceedings before the European Patent Office;

According to SIEMENS, this patent relates only to the DNA fragments covered by claims 1 to 6, which are precisely identified by the restriction sites found at their ends and by their location on the genome, and having the same size, the same beginning and the same end as the genome contained in λ-J19, and does not cover any fragment that may be capable of hybridizing with the claimed fragments;

Moreover, it maintains that claims 1 to 6 are limited to cloned DNA, as opposed to synthetic DNA sequences; in this respect, it argues that this limitation is explained by the fact that INSTITUT PASTEUR had not sequenced the HIV genome on the priority date of patent No. 0 178 978, *i.e.* on 19 September 1984;

It deduces therefrom that the patent only teaches how to produce DNA fragments from the DNA contained in clone λ-J19 and that claim 7, which depends on claims 1 to 6 and which, accordingly, is subject to the same limitations, necessarily covers probes comprising cloned DNA corresponding to the retroviral genome contained in λ-J19;

In the same way, SIEMENS considers that claim 8, which relates to a method comprising a first step of contacting, under hybridizing conditions, a biological sample originating from a person to be diagnosed with HIV and containing RNA in a form suitable for hybridization with the claimed probe, only covers a method using a probe covered by claim 7, such as characterised above, and the detection of the said hybridized probe;

Finally, it considers that claim 11, in its amended wording following the grant and opposition proceedings, does not relate to any of the virus' purified RNA, but only to the complementary RNA contained in λ-J19;

This being set out, one should recall that under Article 69(1) of the European Patent Convention (hereafter EPC), "*the extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims"*;

The Protocol on the Interpretation of Article 69 EPC sets forth, in Article 1 and 2, that "*Article 69 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, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties"* and that *"for the purpose of determining the extent of the protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims*";

INSTITUT PASTEUR rightly argues that only these provisions govern the interpretation of the claims' wording and that the "*file wrapper estoppel*" theory, which consists in also taking into account, to interpret a patent, the statements made by the applicant during the grant or opposition proceedings, cannot be applied;

However, they in no way exclude the possibility for the court, which has to rule on the extent of the protection conferred by the patent, of referring to the wording of the claims as initially filed and of appraising the scope thereof, in particular in light of the amendments made during the grant or opposition proceedings before the European Patent Office;

Claim 1 of the patent application as filed – initially composed of 24 claims – was worded as follows: "*A cloned DNA which contains a DNA which is hybridizable with the genomic RNA of the LAV viruses or a fragment of said hybridizable DNA*";

Claims 13 and 14 – claims 5 and 6 in the granted patent – were worded as follows: "*13. A DNA fragment according to claim 1 which comprises a sequence extending from approximately Kpn I (3500) to approximately Bgl II (6500) of the sequence defined in claim 11.*
14. A DNA fragment according to claim 1 which comprises a sequence extending from approximately Pst (800) to approximately Kpn I (3500) of the sequence defined in claim 11";

During the examination proceedings, document EP-A-0 173 529 was cited as a novelty-destroying prior art document; it is the patent application filed by the NIH on 19 August 1985, claiming priority from patent US 643306 dated 22 August 1984 and entitled "*Molecular clones of the genome of HTLV-III*"; it is not up to the *Tribunal*, which rules on the extent of the protection conferred by the patent and not on its validity, to appraise the relevance of this prior art, being pointed out that, if need be, it was incumbent on INSTITUT PASTEUR to challenge it before the European Patent Office;

On this basis and in a letter dated 6 September 1989, the applicant was asked to "*review the present claims and to further limit them in order to distinguish their matter over EP-A-0173529*" and the examiner specified that "*in this respect the only possibility appears to be the limitation of the present claims to the specific deposited clones.*"

Complying with the examiner's suggestions, INSTITUT PASTEUR amended the wording of its claims; thus, claim 1 as granted is worded as follows: "*A cloned DNA which contains a DNA corresponding to the LAV retroviral genome contained in λJ19 (CNCM I-338)*";

Following the opposition lodged by CHIRON CORPORATION, the Board of Appeal, in a decision issued on 18 November 1999, revoked the decision of the Opposition Division orally pronounced on 22 July 1994, which maintained the patent on the basis of claims 1 to 21 filed during the oral proceedings, and remitted the case to the first instance with the order to maintain the patent on the basis of the auxiliary request as filed during the oral proceedings of 12 May 1999;

Now claim 1 reads as follows: "*A cloned DNA which contains a DNA corresponding to the LAV retroviral genome contained in λJ19 (CNCM I-338), said cloned DNA including LTR elements U3, R and U5 of said retroviral genome*";

As to claims 5 and 6 and as previously set out, they are worded as follows:
5. A cloned DNA fragment whose sequence corresponds to the part of the DNA of λJ19, which extends from approximately Kpn I (3500) to approximately Bgl II (6500) thereof.
6. A cloned DNA fragment whose sequence corresponds to the part of the DNA of λJ19, which extends from approximately Pst I (800) to approximately Kpn I (3500) thereof";

It follows that the amendments made to the claims by INSTITUT PASTEUR during the examination and opposition proceedings – which must be taken into account failing which legal certainty for third parties would be violated – resulted in limiting the scope of the invention, which was voluntarily limited in order to obtain the grant then the maintenance of the patent at issue;

More particularly, it results from above that claims 5 and 6 should be interpreted so as to relate to cloned DNA fragments characterised by their ends, their size and their location on the viral genome as contained in λ-J19;

Dependent claim 7 will be interpreted in the same way, that is as covering a probe composed of one of the fragments taught in claims 1 to 6, whereas claim 8 is limited to a method for the *in vitro* detection of a viral infection due to HIV involving the use of the said cloned DNA probe corresponding to the retroviral genome contained in clone λ-J19;

Finally, it should be considered that claim 11 – which bore number 24 in the patent application as filed and was worded as follows "*The purified RNAs of LAV viruses which have sizes from 9.1 to 9.2 kb*", and which was then amended as follows: "*The purified RNA of LAV virus which has a size from 9.1 to 9.2 kb and which corresponds to the cDNA contained in λ-J19 (CNCM I-338)"* – does not relate to the whole genome of the virus causing AIDS, but to an RNA strand, which is specifically defined by its size, on the one hand, and by its ability to hybridize with the complementary DNA contained in λ-J19, on the other hand;

The scope of claims 5, 6, 7, 8 and 11 of European patent No. 0 178 978 being so defined, there is no reason to examine the claim for invalidity of these claims subsidiarily lodged by SIEMENS.

- On the infringement

INSTITUT PASTEUR considers that the *Versant HIV-1 RNA 3.0 Assay (bDNA)*, marketed by SIEMENS since 2003 in France – which, as stated, are quantitative dosing kits for measuring the viral load in the patient's blood in order in particular to appraise the progress of the disease or the effectiveness of the treatment – implement identically, or at least equivalently, the features of claims 5, 6, 7 and 8 of European patent No. 0 178 978;

Furthermore, it maintains that the use of these assays requires a step of purification of the whole genomic RNA of the AIDS virus, hence committing contributory infringement with respect to claim 11 of the said patent;

Each of these charges should be examined.

** On the direct infringement or the infringement by equivalence of claims 5 to 8*

Under Article L. 613-3 of the French Intellectual Property Code, "*The following shall be prohibited, save consent by the owner of the patent:*
a) Making, offering, putting on the market or using a product which is the subject matter of the patent, or importing or stocking a product for such purposes;
b) Using a process which is the subject matter of the patent or, when the third party knows, or it is obvious in the circumstances, that the use of the process is prohibited without the consent of the owner of the patent, offering the process for use on French territory";

The parties agree to consider that the implementation of the *Versant HIV-1 RNA 3.0 Assay (bDNA)* quantitation kit, defined in its datasheet attached to the *saisie-contrefaçon* report drafted on 9 June 2005 at the BICHAT-CLAUDE BERNARD Hospital as "*an assay for molecular hybridization using oligonucleotide probes with signal amplification for the direct in vitro quantitation of human immunodeficiency virus (HIV) type 1 in the plasma of infected patients*", comprises five successive steps:

- a first step of release and capture of the viral RNA and of hybridization of the target probes with the viral RNA; it consists in placing blood samples on the plates of the quantitation kits, then in adding lysis reagents and diluents releasing the viral RNA from the virions by the lysis of the viral capsule as well as capture probes and target probes, which partially hybridize with the viral RNA, and finally in a washing after incubation to remove the remaining probes and the nucleotide acids other than those captured;

- a second step of hybridization of the pre-amplification probes with the target probes, which are not complementary to the viral RNA;

- a third step of hybridization of the amplification probes with the pre-amplification probes to create a branched DNA or bDNA complex;

- a fourth step of hybridization of label probes, labelled with alkaline phosphatase, with the branched DNA complex;

- a fifth step of detection by incubation of the complex with a chemiluminiscent substrate reacting with alkaline phosphatase of the label probes, the emission of luminous signals being proportional to the quantity of viral RNA in each sample;

It is also established that the capture probes used in the first step of the allegedly infringing kit are composed of 17 individual capture extenders while the target probes are composed of 81 individual target extenders;

With reference to the datasheet of the accused assay, according to which these probes "*bind to the different regions of the pol gene of the viral RNA*" and which moreover specifies that "*Versant® HIV-1 RNA 3.0 Assay (bDNA) is standardized in copies/mL by means of an RNA transcript of 3.6 kb containing almost all of the pol gene of the SF-2 strain of HIV-1"*, INSTITUT PASTEUR argues that the 98 probes at issue bind to the sequence of bases of HIV-1 comprised between 2085 and 5098 in the HXB2 numbering scheme (*i.e.* between 1555 and 4568 according to the patent numbering) and corresponding to the region of the *pol* gene;

In support of its arguments, it produces a report drafted on 30 May 2008 by Doctor Jacques-H.M. COHEN, who, after having analysed the kit in dispute, concludes in these words: "*all the fragments tested coming from the pol gene lead to a positive signal in the Versant HIV-1 RNA 3.0 kit whereas the fragments of the env gene give no signal. (...) The bDNA probes of the Versant HIV-1 RNA 3.0 (bDNA) kit are well located in the pol region of the HIV virus"*;

Recalling that the description of European patent No. 0 178 978 states that "*the invention also relates more specifically to cloned probes which can be made starting from any DNA fragment according to the invention*", it deduces that the DNA fragments covered by claim 5 – corresponding to DNA comprised between 3500 and 6500 (*i.e.* from 4030 to 7030 in the HBX2 numbering scheme) – and the DNA fragments covered by claim 6 – corresponding to DNA comprised between 800 and 3500 (*i.e.* from 1330 to 4030 in the HBX2 numbering scheme) – "*largely*" cover the *pol* gene revealed by the *Versant HIV-1 RNA 3.0 Assay (bDNA)*;

Therefore, according to it, the probes used in the kits marketed by SIEMENS are identical to the probes protected by claim 7, including in their dependence on claims 5 and 6;

Adding that the detection in the accused assay is performed by incubation of the complex with a chemiluminiscent substrate – which, incidentally, is in no way disputed –, INSTITUT PASTEUR concludes that the method taught in patent claim 8, which, as previously set out, covers a method comprising a first step of hybridization of target probes as defined in claim 7 with the viral RNA and a second step of detection of the hybridized probe, is implemented;

But it has been previously stated in the grounds devoted to the scope of European patent No. 0 178 978 that claims 5 and 6 – which relate to "*a cloned DNA fragment whose sequence corresponds to the part of the DNA of λ-J19, which extends"*, regarding claim 5, *"from approximately Kpn I (3500) to approximately Bgl II (6500) thereof"* and, regarding claim 6, "*from approximately Pst I (800) to approximately Kpn I (3500) thereof"* – should be interpreted so as to relate to cloned DNA fragments which are defined by their restriction sites and characterised by their ends, their size and their location on the viral genome as contained in λ-J19;

It emerges from the above mentioned datasheet that the target probes and the capture probes used in the *Versant HIV-1 RNA 3.0 Assay (bDNA)* kit are composed of synthetic oligonucleotides and not of cloned DNA;

Moreover, the 98 probes at issue – namely, as set out, 17 capture probes and 81 target probes, each composed of approximately 20 to 30 bases – if it is assumed that they are placed end to end, bind to the sequence of bases of the HIV-1 virus comprised between 2085 and 5098 in the HXB2 numbering scheme (*i.e.* between 1555 and 4568 according to the patent's numbering) and accordingly are located neither on the fragment of claim 5, which corresponds to DNA comprised between 3500 and 6500 (*i.e.* from 4030 to 7030 in the HBX2 numbering scheme), nor on the fragment of claim 6, which corresponds to DNA comprised between 800 and 3500 (*i.e.* 1330 and 4030 in the HBX2 numbering scheme);

It follows that the fragments composing the accused probes do not identically implement the features of patent claims 5 and 6, which, as rightly supported by the defendant, are independent from each other and cannot be combined to appraise the infringement;

Claim 7, which covers "*a probe for the in vitro detection of LAV which consists of a DNA according to any of claims 1 to 6*", is not implemented either since it depends directly on claims 5 and 6, for which infringement has been dismissed;

In the same way, claim 8, which relates to "*a method for the in vitro detection of viral infection due to the LAV viruses which comprises contacting a biological sample originating from a person to be diagnosed for LAV infection and containing RNA in a form suitable for hybridization with the probe of claim 7 under hybridizing conditions and detecting the hybridized probe"* and which accordingly, as stated above, is limited to a method using probes composed of cloned DNA fragments corresponding to the retroviral genome contained in clone λ-J19, is not infringed failing implementation of claims 5, 6 and 7 on which it depends;

INSTITUT PASTEUR alternatively argues that the means, which is constituted by the use, as probes, of whole fragments of 2,700 bases (claim 6) or of 3,000 bases (claim 5), is infringed by equivalence by the use, in the kits marketed by SIEMENS, of probes that totally or partially cover these sequences and fulfil the same new function of DNA-RNA hybridization to achieve a similar result, which consists in detecting the hybridized probe for diagnosing the disease;

However, it has just been recalled that claim 8 does not protect, as supported by the claimant, a new general means for detecting and quantitating the AIDS virus by the hybridization of DNA probes labelled with the viral RNA – such a detection method being already disclosed in the European patent application filed on 19 August 1985 by the NIH, which claims priority from patent US 643306 of 22 August 1984, but a method using probes composed of cloned DNA fragments corresponding to the retroviral genome contained in λ-J19, considering the limitations made by the patentee to the claims' wording during the examination and opposition proceedings before the European Patent Office;

It follows that the patented means, that is the use of probes composed of DNA fragments, is only new in its form, as the fulfilled function of hybridization with the viral RNA for detecting the disease is known;

The infringement by equivalence, which, in the present case, cannot result from the identity of functions, can be constituted only if the very form of the patented means is implemented in an equivalent form and in what characterizes its patentability, namely, in the present case, probes composed of cloned DNA fragments defined by their restriction sites and corresponding to the retroviral genome contained in clone λ-J19;

The accused capture probes and target probes, which each comprise, as stated, approximately 20 to 30 synthetic nucleotides and which bind to the sequence of bases of the HIV-1 virus comprised between 1555 and 4568 cannot be considered the equivalent of the probes constituted by the cloned DNA fragments according to patent claims 1 to 6;

Nor can the infringement by equivalence be held;

Therefore, INSTITUT PASTEUR's claims for infringement of claims 5, 6, 7 and 8 of European patent No. 0 178 978 will be dismissed without it being necessary to resort to the provisions of Article L. 615-5-1 of the French Intellectual Property Code; in this case, the reversal of the burden of proof, sought by INSTITUT PASTEUR, is irrelevant since the dismissal of its claims does not result from its difficulties in proving the alleged infringement, but from the absence of infringement.

* *On the contributory infringement of claim 11*

According to Article L. 613-4, 1° of the French Intellectual Property Code "*It shall also be prohibited, save consent by the owner of the patent, to supply or offer to supply, on French territory, to a person other than a person entitled to work the patented invention, the means of implementing, on that territory, the invention with respect to an essential element thereof where the third party knows, or it is obvious from the circumstances, that such means are suited and intended for putting the invention into effect*";

Claim 11 of European patent No. 0 178 978 covers "*the purified RNA of LAV virus which has a size from 9.1 to 9.2 kb and which corresponds to the cDNA contained in λJ19 (CNCM I-338)"*;

INSTITUT PASTEUR considers that the different items seized during the *saisie-contrefaçon* establish that the whole genomic RNA of the AIDS virus is purified – or released – with the *Versant HIV-1 RNA 3.0 Assay (bDNA)*, its datasheet specifying in particular that "*HIV-1 is first concentrated from plasma by centrifugation"* then "*after HIV-1 genomic RNA is released from the virions, the RNA is captured on a solid support through capture probes*";

It deduces therefrom that the supply by SIEMENS of kits containing the reagents, the specific means and the experimental protocol for isolating the viral RNA present in the infectious viral particles found in the patient, and the availability of its datasheet, constitute contributory infringement acts with respect to an essential means of the invention, *i.e.* the viral RNA of the HIV-1 virus covered by claim 11;

It should be recalled that, in compliance with the aforementioned provisions, the supply of means only constitutes an infringement act provided that the supplied means – which, as rightly supported by the claimant, are not necessarily claimed by themselves – relate to an essential element of the invention, hence contributing to its result;

Therefore, SIEMENS cannot draw argument from the fact that claim 11 is a product claim and not a process claim to conclude that the accused quantitation kits do not relate to an element constituting the claim as such circumstance is not *per se* likely to exclude contributory infringement;

However, as stated, claim 11 should be interpreted as not relating to the whole genome of the virus causing AIDS, but to an RNA strand precisely defined by its size, on the one hand, and by its ability to hybridize with the complementary DNA contained in λ-J19, on the other hand, even though Professor MONTAGNIER states in this instance, without being contradicted, that "*it is from the DNA contained in λJ19 that we could sequence the whole HIV-1 genome afterwards"*;

If it is established, without it being necessary to resort to expert proceedings, that the whole viral RNA in the blood samples coming from patients is used in the allegedly infringing quantitation kits, however it is in no way shown or alleged that these kits would allow the accurate isolation of the virus RNA having a size of 9.1 to 9.2 kb and corresponding to the complementary DNA contained in clone λ-J19, that is RNA having ends corresponding to those of DNA of λ-J19;

Therefore, in the same way, INSTITUT PASTEUR's claims for contributory infringement of claim 11 of European patent No. 0 178 978 will be dismissed.

- On the counterclaim for damages for abuse of procedure

Initiating a court action in principle constitutes a right and turns into an abuse, which may give rise to a claim for damages, only in case of malice, bad faith or gross mistake equipollent to deceit;

The defendant's claim in this respect will be dismissed since it does not prove any intention to harm or any blameful lack of heed from INSTITUT PASTEUR, which could have misjudged the extent of its rights, and since it does not establish damage other than the one suffered from the defence costs incurred.

- On the further claims

There is reason to order INSTITUT PASTEUR, the unsuccessful party, to pay the costs, which will be collected in compliance with the provisions of Article 699 of the French Civil Procedure Code;

Moreover, INSTITUT PASTEUR should be ordered to pay to SIEMENS, which had to incur unrecoverable costs to assert its rights, compensation with respect to Article 700 of the French Civil Procedure Code, which is fairly set at 150,000 euros;

The provisional enforcement, which is irrelevant here, cannot be ordered.

ON THESE GROUNDS

The *Tribunal,* ruling in open court, pronouncing a judgment issued in first instance, after hearing all the parties and made available at the court clerk's office,

- DISMISSES INSTITUT PASTEUR's claims;

- DISMISSES SIEMENS HEALTHCARE DIAGNOSTICS's counterclaim for damages for abuse of procedure;

- ORDERS INSTITUT PASTEUR to pay 150,000 euros to SIEMENS HEALTHCARE DIAGNOSTICS in application of the provisions of Article 700 of the French Civil Procedure Code;

- ORDERS INSTITUT PASTEUR to pay the costs, which will be collected in compliance with the provisions of Article 699 of the French Civil Procedure Code;

- STATES that there is no reason to pronounce the provisional enforcement.

Ordered and adjudged in PARIS on 28 May 2010.

The Court Clerk The Presiding Judge