T R I B U N A L
D E GRANDE I
N S T A N C E
DE PARIS

3rd chamber 2nd section

RG NO.: **08/08679**

MINUTE

Summons dated: June 24, 2005

JUDGMENT
issued on May 28, 2010

DEMANDERESSE

INSTITUT PASTEUR
25-28 rue du Docteur Roux
75015 PARIS

represented by Marina COUSTE, lawyer at the PARIS bar, courtroom L295

DEFENDER

SIEMENS HEALTHCARE DIAGNOSTICS formerly known as BAYER DIAGNOSTICS rćprćsentée par Mr.juan Manuel Martin DUAIGUES.
9 Boulevard Finot
93200 SAINT DENIS

represented by Pierre VERON, attorney at the PARIS bar, checkroom P24, and Thomas BOUVET, attorney at the LYON bar.

COMPOSITION OF THE COURT DURING DF.S DEBATES

Vëronique RENARD, Vice-President
Eric HALPHEN, Vice-President
Sophie CANAS, Judge,

Expeditions exécutoires délivrées Ie : 31/5/2010

COMPOSITION OF THE COURT AT THE TIME OF PRONOUNCEMENT

Véroniqiie RENARD, Vice-Chairman
Soohie CANAS, Judge, *signatory of the decision*
Anne CHAPLY, Judge

assisted by Jeanine ROSTAL, FF de GvefYiev,.signatory *of the decision*

DEBATES

At the hearing of March 1 2, 2010
held in open court

JUDGMENT

Delivered by delivery of the decision to the clerk's office
Contradictory
in the first instance

FACTS, PROCEDURF. AND CLAIMS OF THE **PARTIES**

L'INSTITUT PASTEUR, a public utility foundation, is the owner of European patent no. 0 178 978, filed on September 17, 1985 under priority of British patent no. 8423659 of September 19, 1984, granted on February 6, 1991 and entitled *"Cloned DNA sequences hybridizable with genomic RNA of lymphadenopathy-associated* virtis *(LAV)"*.

Since 2003, BAYER DIAGNOSTICS has been marketing in France, under the name *Versant HIV-1 RNA 3.0 Assay (bDNA),* kits for the quantitative diagnosis of the human immunodeficiency virus (HIV) responsible for acquired immunodeficiency syndrome (AIDS) in humans.

Believing that these detection kits and the reagents they contain reproduce the characteristics of the invention described in patent EP 0 178 978, and after having carried out duly authorized seizure operations on June 09, 2005, on the one hand at the headquarters of BAYER DIAGNOSTICS located in PUTEAUX (92), and on the other hand on the premises of the BICHAT-CLAUDE BERNARD Hospital located in PARIS 18e , INSTITUT PASTEUR has, according to a bailiff's deed dated June 24, 2005, served a writ on BAYER DIAGNOSTICS for infringement of claims 5, 7, 8 and 11 of European patent no. 0 178 978, seeking, in addition to measures of prohibition, confiscation for the purposes of destruction and publication, as well as the production of accounting elements, payment of damages and an indemnity under article 700 of the French Code of Civil Procedure, all with the benefit of provisional execution.

The case was successively struck out by orders dated November 04, 2005 and March 09, 2007, and lastly reinstated at the status hearing on October 16, 2008.

In its summary submissions served on September 03, 2009, to which it is expressly referred, INSTITUT PASTEUR asks the Court to :
on a principal basis,
- reject the incidental claims and objections raised by Bayer Diagnostics (now Siemens Healthcare Diagnostics),
- To see, declare and rule that European patent no. 173 529 dit *Gallo* and Doctor Arya's article are not enforceable against European patent no. 178 978 insofar as they have been improperly disclosed,
- reject all the claims, aims and conclusions put forward by Bayer Diagnostics (now Siemens Healthcare Diagnostics),
- To see, declare and hold that Bayer Diagnostics (now Siemens Healthcare Diagnostics) has infringed European patent EP 178 978B2 by importing, using, possessing, offering for sale and selling reagents and kits, and by supplying or offering to supply to third parties the means necessary for the purification of HIV-1 RNA and for the implementation of diagnostic methods, infringing in particular claims 5, 6, 7, 8 and 11 of the French part of European patent 178 978 B2,
in the alternative,
- appoint such expert as the Court may deem fit to determine whether the AIDS virus RNA purified in the *Versants HIV-1 RNA 3.0 Assay (bDNA)* necessarily corresponds to the complete genomic RNA specific to the AIDS virus as first defined by claim 11 of the patent in this case,
principal and subsidiary,
- order Bayer Diagnostics (now Siemens Healthcare Diagnostics) to make good the damage caused to Institut Pasteur, and to pay it the sum of 2 million euros as a provision,
- appoint such expert as it sees fit, with the task of assessing the loss suffered by Institut Pasteur by obtaining all information likely to enable it to carry out the said calculation, including the sales generated using the apparatus dedicated to the use of the infringing products, and order Bayer Diagnostics (now Siemens Healthcare Diagnostics) to provide all certified accounts of the sales it has generated since the sale of these products in France,
- authorize Institut Pasteur to publish the judgment in ten newspapers or periodicals of its choice, at the expense of Bayer Diagnostics (now Siemens Healthcare Diagnostics) and not exceeding 20,000 euros per publication, as additional damages,
- declare that the sentences handed down will cover all acts of infringement committed up to the date of the final decision on the present application or the expiry of the patents,
- order, in view of the urgency of the matter, provisional execution of the judgment notwithstanding appeal and without the provision of security,
- order Bayer Diagnostics (now Siemens Healthcare) to pay the costs.

Diagnostics) to pay Institut Pasteur the sum of 200,000 euros pursuant to article 700 of the French Code of Civil Procedure, as well as all costs and expenses, which will be awarded to Maître Marina COUSTE, avocat à la Cour, in accordance with article 699 of the French Code of Civil Procedure.

In its final pleadings dated November 26, 2009, to which reference is likewise made, SIEMENS HEALTHCARE DIAGNOSTICS, formerly known as BAYER DIAGNOSTICS and hereinafter referred to as SIEMENS, seeks the following orders:
- declare and rule that claims no. 5, 6 and 7 of patent no. 0 178 978 do not have the broad scope attributed to them by INSTITUT PASTEUR, but that they cover only the literally claimed fragments characterized by their extremities, size and position on the viral genome as contained in clone Z-J19,
- declare that claim no. 8 does not have the scope attributed to it by the INSTITUT PASTEUR, but only covers a detection method using a probe of claim no. 7, i.e. a probe consisting of one of the fragments of claims nos. 1 to 6,
- rule that claim no. 11 of patent no. 0 178 978 cannot be interpreted, as claimed by INSTITUT PASTEUR, to cover any purified RNA of the LAV virus larger than 9.2 kb, regardless of whether it corresponds to the complementary DNA contained in clone Z-J19,
- consequently, declare that by importing and marketing its quantification kit, SIEMENS is not guilty of direct infringement of claims no. 5, 6 and 7, nor of infringement by supply of means of claims no. 8 and 11 of patent no. 0 178 978,
- in the alternative, if claims no. 5, 6, 7, 8 and 11 are to be interpreted as claimed by INSTITUT PASTEUR, declare these claims invalid for lack of description or novelty,
in any case,
- dismiss INSTITUT PASTEUR's claims against SIEMENS for infringement of patent no. 0 178 978,
- order INSTITUT PASTEUR to pay SIEMENS the sum of 200,000 euros as compensation for the damage suffered as a result of the abusive nature of the present proceedings,
- order INSTITUT PASTEUR to pay SIEMENS the sum of 400,000 euros pursuant to Article 700 of the French Code of Civil Procedure, as well as all costs, which will be recovered in accordance with Article 699 of the French Code of Civil Procedure.

The closing order was issued on January 28, 2010.

REASONS FOR DECISION

Whereas it should be noted at the outset that SIEMENS no longer raises the issue of the millity of the seizure reports drawn up on June 09, 2005 in its latest pleadings, and that L'INSTITUT PASTEUR's comments on this point are therefore irrelevant.

- Historical and scientific background

Whereas, prior to examining the object of the invention and in order to better appreciate its scope, it is appropriate to recall the history of research into the virus responsible for AIDS (Acquired Immunodeficiency Syndrome), a new disease which appeared in 1980 throughout the world, and more particularly in the United States, and which was officially designated as such on July 27, 1982,

Since the early 1980s, this research has been carried out mainly by two parallel teams, one French, led by Professor MONTAGNIER at the INSTITUT PASTEUR, the other American, led by Professor GALLO - himself the originator in 1980 of the discovery of the first human retrovirus, the human T lymphocyte virus type I or HTLV-I - at the Nationa) Institutes of Health (NIH), an agency of the US Department of Health and Human Services;

That it is now common knowledge that, although the NIH team officially announced in 1984 that it had isolated the virus responsible for AIDS, named HTLV-III because, according to them, it belonged to the HTLV (Human T-cell Lymphotropic Virus) family of oncoviruses, in fact, it was Professor MONTAGNIER's team who first described the AIDS virus, called LAV (for Lymphadenopathy-Associated Virus), which they rightly claimed belonged to the lentivirus family, in an article published in *Science* magazine on May 20, 198? ;

The authorship of this discovery gave rise to a major dispute between Professors GALLO and MONTAGNIER, which was brought to an end in 1987 with the conclusion of an agreement between INSTITUT PASTEUR and the U.S. Department of Health and Human Services (HHS), and the publication of a joint press release by the two institutes recalling the chronology of their respective contributions, and in particular attributing to the French team the identification in May 2003 of the LAV retrovirus, different from HTLV;

Following the identification of the virus responsible for AIDS, research in 1984 focused on characterizing and sequencing the genomes of the HTLV-III, LAV and ARV (for Aids-Associated Retroviius, isolated by Professor LEVY of San Francisco University) viruses, the publication in January-February 1985 of the nucleotide sequences forming the viral RNA (RiboNucleic Acid) - mainly composed of the *gag, pol* and env genes - confirming that the viruses studied by each team were identical;

That the single acronym HIV for Human Immunodeficiency Virus (in French VIH pour virus d'immunodéficience humaine) was thus proposed in 1956 by the International Committee on Taxonomy and definitively replaced the terms LAV and HTLV-III, it being understood that a second virus responsible for AIDS - called HIV 2 - was discovered in 1985, but that only the above-mentioned virus, and since that date called HIV 1, is at issue in the present dispute;

Knowledge of the HIV genome has made it possible to develop, alongside immunoassays to detect the presence of proteins synthesized by viral RNA or the presence of specific antibodies, genetic tests that can, using probes made up of complementary strands of DNA or RNA specific to the target gene whose presence is being sought, to detect the presence of the viral genome itself, thereby enabling early diagnosis of the disease, essential in particular for the safety of blood donations used in blood transfusions;

That both the patented invention opposed in the present case and the allegedly infringing *Versant HIV-1 RNA 3.0 Assay (bDNA)* quantitative assay kit concern this second category of tests.

- Subject matter of European patent no. 0 178 978

Whereas European patent no. 0 178 978 filed on September 17 1985 under British priority of September 19, 1954 and granted on February 06, 1991 was the subject of opposition proceedings before the European Patent Office and was upheld, with amended claims, by decision of the Board of Appeal on November 18, 1999;

That the invention, entitled *"Cloned DNA sequences hybridizable with the genomic RNA of lymphadenopathy-associated virus (LAV)",* relates to cloned DNA sequences capable of hybridizing with the genomic RNA and DNA of lymphadenopathy-associated virus (LAV) - now called HIV - , on a process for preparing said sequences and on their uses, more particularly on stable probes comprising a DNA sequence which can be used for the detection of LAV or related viruses or DNA proviruses, in any medium, in particular in biological samples containing any of them;

That the descriptive part recalls that the detection methods available to date are based on the recognition of viral proteins and that a method of this type is described in European patent application EP-A-138 667, entitled *"Antigens, means and method for the diagnosis of lymphadenopathy and acquired immunodepression syndrome",* filed on September 14, 1984 under priority of British patent application no. 83 24 800 filed on September 15, 195?

That it is stated that the aim of the invention is to propose new means which should not only be equally useful for the detection of LAV or related viruses, but also offer greater flexibility, particularly in the detection of specific parts of the genomic DNA of said viruses, whose expression products are not always detectable by immunological methods;

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Whereas the patent consists of eleven claims, as follows

1. Nested DNA containing DNA corresponding to the retroviral genome of lymphadenopathy virus (LAV) contained in M19 (CNCM 1-338), this cloned DNA comprising the U3, R and US elements of this retroviral genome.

2. A DNA according to claim 1 which is a cDNA.

3. Nailed DNA containing a DNA which consists of :
- into a fragment of the 3' end of the DNA contained in Ml9 (CNCM 1-338) corresponding to the LAV retroviral genome and up to 2.5 kb containing the following restriction sites, in the following respective orders (from 1 end 3 to 1 end 5):
1) either Hind III, Sac I, Bgl II,
2) i.e. Hind III, Sac I, Bgl II, Bgl II, Kpn I,
3) either Hind III, Sac I, Bgl II, Bgl II, Kpn I, Xho I, Bam HI, Hind III, Bgl

4. A nested DNA fragment whose sequence corresponds to the part of Ml9 DNA that extends approximately from the Kpn I site (6100) to the Bam HI site (8150).

5. A nested DNA fragment whose sequence corresponds to the part of Ml9 DNA that extends approximately from the Kpn I site (3500) to the Bgl II site (6500).

6. A nested DNA fragment whose sequence corresponds to the part of H19 DNA that extends approximately from the Pst I site (800) to the Kpn I site (3500).

7. Probe for in vitro detection of LAV consisting of a DNA according to any of claims 1 to 6.

8. A method for the in vitro detection of viral infection due to LAV viruses, comprising contacting a biological sample from a person in whom LAV infection is to be detected 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, more particularly a plasmid, for the transformation of eukaryotic or prokaryotic cells, containing an insertion fragment according to any one of claims 1 to 6.

10. Microorganism, prokaryotic or eukaryotic cell, transformed by a vector according to claim 9.

11. RNA purified from LAV virus, 9.1 to 9.2 kb in size, corresponding to the complementary DNA contained in H19 (CNCM 1-338).

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Whereas INSTITUT PASTEUR invokes in the present proceedings only claims 5, 6, 7, 8 and 1 of the said patent.

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

Whereas INSTITUT PASTEUR maintains that patent no. 0 178 978 enabled, for the first time, the detection of very small quantities of virus, the causal agent of AIDS, within a very short time, which was decisive in stopping the risks of contamination and encouraging the introduction of antiretroviral treatment and the monitoring of its efficacy, and that the Court must therefore, in its assessment of the facts of the case, take into account the pioneering nature of this invention;

More specifically, he claims that claim 8 protects a novel general means for detecting and quantifying the AIDS virus by hybridizing labeled DNA probes with viral RNA, said probes being defined by claim 7, which refers to claims 1 to 6 - reproduced above - and in particular to claims 5 and 6, which identify the *pol* gene region specific to said virus;

He therefore considers that the patent covers all DNA probes, even if they are not expressly disclosed and notwithstanding any form of variation or improvement, on the sole condition that they are capable of hybridizing with AIDS virus RNA to ensure detection;

Continuing its reasoning, INSTITUT PASTEUR also considers that claim 11 of the opposed patent protects the purified RNA of the virus responsible for SDA in its entirety, which corresponds to the complementary DNA contained in clone M19, and not a particular fragment isolated at random;

Whereas SIEMENS essentially argues that the applicant is attempting to give claims 5, 6, 7, 8 and 11 of its patent the scope of previous claims which it was forced to renounce during the grant and opposition proceedings before the European Patent Office;

In her view, this bi'evet could only cover the DNA fragments covered by claims 1 to 6, i.e. fragments precisely identified by the restriction sites at their ends and their position on the genome, and having the same size, the same beginning and the same end as the genome contained in ZI19, and not cover any fragment capable of hybridizing with the claimed fragments;

That it further maintains that claims 1 to 6 are limited to cloned DNA, as opposed to synthetic DNA sequences, arguing in this respect that this limitation is explained by the fact that the INSTITUT PASTEUR had not sequenced the VII-I genome on the priority date of patent no. 0 178 978, i.e. September 19, 1984;

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She concludes that the patent only teaches how to obtain DNA fragments from the DNA contained in clone M19, and that claim 7, which is dependent on claims 1 to 6 and therefore subject to the same limitations, necessarily covers probes containing cloned DNA corresponding to the retroviral genome contained in ZJ19,

In the same way, SIEMENS considers that claim 8 - which relates to a process comprising a first step of bringing into contact, under hybridizing conditions, a biological sample from a person in whom HIV infection is to be tested and containing RNA in a form suitable for hybridization with the claimed probe, and a second step of detecting the hybridized probe - covers only a process involving the use of a probe of claim 7, as characterized above, and the detection of said hybridized probe;

Finally, it considers that claim 11, as amended following the grant and opposition proceedings, does not relate to any RNA purified from the virus, but only to the complementary RNA contained in U19 ;

Whereas, having said this, it should be recalled that under Article 69 (1) of the European Patent Convention (hereinafter EPC), *"The scope of protection conferred by the European patent shall be determined by the claims. However, the description and drawings shall serve to interpret the claims";*

Articles 1" and 2 of the Interpretative Protocol to Article 69 of the EPC state that *"Article 69 is not to be interpreted as meaning that the scope of protection conferred by the European patent is determined in the narrow and literal sense of the text of the claims, and that the description and drawings serve only to dispel any ambiguities which the claims may conceal. Nor is it to be interpreted as meaning that the claims serve only as a guideline and that protection also extends to what, in the opinion of a person skilled in the art who has examined the description and drawings, the patentee intended to protect. Article 69, on the other hand, must be interpreted as defining a position between these extremes which ensures both fair protection for the patent proprietor and a reasonable degree of legal certainty for third parties"* and that *"in determining the scope of protection conferred by the European patent, due account shall be taken of any element equivalent to an element indicated in the claims";*

INSTITUT PASTEUR rightly argues that only these provisions govern the interpretation of the content of the claims and that the theory of "island *wrapper estoppel",* which consists in also taking into account, when interpreting a patent, declarations made by the applicant during grant or opposition proceedings, cannot be applied,

That, however, they in no way exclude the possibility for the court called upon to rule on the scope of protection conferred by the patent to refer to the content of the claims as initially filed and to assess their scope, in particular with regard to the amendments made in the course of the grant or opposition proceedings before the European Patent Office;

Now whereas claim 1 of the application as filed - initially composed of 24 claims - was worded as follows: *"Nested DNA containing DNA hybridizable with the genomic RNA of LAV viruses or a fragment of said hybridizable DNA",*

That claims 13 and 14 - which have become claims 5 and 6 in the patent granted
- were written as follows:
"13. A DNA fragment according to claim 1 which comprises a sequence extending from approximately the Kpn I site (3500) to approximately the Bgl II site (6500) of the sequence defined in claim 11.
14. A DNA fragment according to claim 1 which comprises a sequence which extends from approximately the Pst site (800) to approximately the Kpn I site (3500) of the sequence defined in claim 11." ,

During the examination procedure, document EP-A-0 173 529 was cited as an anteriority destroying novelty - i.e. the patent application filed on August 19, 1985 by the NIH under the priority of patent US 643306 of August 22, 1984 and entitled *Clones moléculaires du génome du HTLV-III' -,* It is not for the Court of First Instance, ruling on the scope of protection conferred by the title and not on its validity, to assess the relevance of this document, given that it was incumbent on INSTITUT PASTEUR to challenge it before the European Patent Office;

On this basis, and in a letter dated September 06, 1989, the applicant was asked to *"revise the present claims and limit them again in order to distinguish their subject matter from patent application IP-A-0173529",* the examiner specifying that *"in this respect, the only possib ility seems to be the limitation of the present claims to the specific clones filed",*

In response to the examiner's suggestions, INSTITUT PASTEUR amended the content of its claims, with claim 1 as issued now reading as follows: "*Nested DNA containing DNA corresponding to the retroviral genome of lymphadenopathy virus (LAV) and contained in Ml9 (CNMC 1-38)". ,*

That following the opposition filed by CHIRON CORPORATION, the Board of Appeal in a decision rendered on November 18, 1999 annulled the decision of the Opposition Division rendered orally on July 22, 1994 to maintain the patent on the basis of claims 1 to 21 filed during the oral proceedings and remitted the case to the first instance with 1 instruction to maintain the patent on the basis of the subsidiary request as filed during the oral proceedings of May 12, 1999;

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Claim 1 now reads as follows: *"Nested DNA containing DNA corresponding to the retroviral genome of lymphadenopathy virus (LAV) and contained in H19 (CNCM 1-338), said nested DNA comprising the U3, R and US elements of said retroviral genome"* ,

As previously explained, claims 5 and 6 are worded as follows:
"5. A nested DNA fragment whose sequence corresponds to the part of H19 DNA that extends approximately from the Kpn I site (3500) to the Bgl II site (6500).
6. A nested DNA fragment whose sequence corresponds to the portion of H19 DNA that extends from approximately the Pst I site (800) to approximately the Kpn I site (3500)",

It follows that the amendments made by the INSTITUT PASTEUR to the claims during the examination and opposition proceedings - which must be taken into account unless the legal certainty of third parties is prejudiced - had the effect of limiting the scope of the invention, which was voluntarily restricted in order to obtain the grant and then the maintenance of the patent in question;

More particularly, it follows from the foregoing that claims 5 and 6 must be interpreted as relating to cloned DNA fragments characterized by their ends, size and position on the viral genome as contained in clone XJ19 ;

That dependent claim 7 will similarly be construed as covering a probe consisting of one of the fragments taught by claims 1 to 6, whereas claim 8 is limited to a method for the in vitro detection of rine viral infection due to HIV involving the use of said cloned DNA probe and corresponding to the retroviral genome contained in clone ZJ19;

Finally, it must be considered that claim 11 - which in the application as filed bore number 24 and was worded as follows: "*Purified RNAs of LAV viruses having a size of 9.1 to 9.2 kb",* then amended to read: *"Purified RNAs of LAV viruses having a size of 9.1 to 9.2 kb and corresponding to the complementary DNA contained in M19 (CNCM 1-338)".* - does not refer to the entire genome of the virus responsible for AIDS, but to a strand of RNA precisely defined, on the one hand by its size, and on the other by its ability to hybridize with the complementary DNA contained in XJ19 ,

Whereas the scope of claims 5, 6, 7, 8 and 11 of European patent no. 0 178 978 having thus been defined, there is no need to examine SIEMENS' subsidiary request for invalidity of these claims.

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- Infringement

Whereas INSTITUT PASTEUR considers that the *Versant HIV- 1 RNA 3.0 Assay (bDNA)* tests marketed since 2003 in France by SIEMENS - which have been described as quantitative assay kits designed to measure the viral load in a patient's blood in order, in particular, to assess the course of the disease or the efficacy of the treatment - reproduce identically, or at least equivalently, the features of claims 5, 6, 7 and 8 of the patent.
european patent no. 0 178 978 ;

It further maintains that the implementation of these tests requires a purification step of the complete genomic RNA of the AIDS virus, thus infringing claim 11 of the said patent by supplying means;

That it is appropriate to examine each of these grievances.

** Infringement by reproduction or equivalence of claims 5 to 8*

Whereas under the terms of Article L.613-3 of the French Intellectual Property Code, *"In the absence of the consent of the patent owner, the following are prohibited :*
a) Manufacturing, offering, marketing, using, importing or possessing the product covered by the patent for the aforementioned purposes,
b) The use of a process covered by the patent or, when the third party knows or when circumstances make it obvious that the use of the process is prohibited without the consent of the patent owner, the offer of its use on French territory",

Whereas the parties agree that the use of the *Versant HIV-1 RNA 3.0 Assay (bDNA),* defined in its data sheet appended to the seizure-infringement report drawn up on June 09, 2005 at the BICHAT-CLAUDE BERNARD hospital as a *"molecular hybridization test using oligonucleotide probes with signal amplification for the direct in vitro quantification of Ç'pe 1 human immunodeficiency virus (HIV) in the plasma of infected patients",* comprises five successive steps:
- a first step of release and capture of viral RNA and hybridization of target probes to viral RNA, which consists in placing blood samples on quantification kit plates, then adding lysis reagents and diluents that release viral RNA from virions by lysis of the viral capsule, as well as capture probes and target probes that partially hybridize to viral RNA, and finally washing after incubation to eliminate residual probes and nucleotide acids other than those captured,
- a second step of hybridizing the so-called pre-amplifier probes with the target probes, non-complementary to the viral RNA,
- a third step of hybridizing the enhancer probes to the pre-amplifier probes to create a branched DNA complex or bDNA,

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- a fourth step of hybridizing the alkaline phosphatase-labeled marker probes to the branched DNA complex,
- a fifth stage of detection by incubating the complex with a chemiluminescent substrate which reacts with the alkaline phosphatase of the marking probes, the emission of light signals being proportional to the quantity of viral RNA present in each sample;

It is also common ground that the capture probes used in the first stage of implementation of the allegedly infringing kit are made up of 17 individual capture extenders, while the target probes are made up of 81 individual target extenders;

Referring to the data sheet for the test in question, which states that these probes *"bind to different regions of the viral RNA pol gene",* and which also specifies that *"Versants HIV-1 RNA 3.0 ASSAY (bDNA) is standardized in copies/ml using a 3.6 kb RNA transcript containing almost the entire pol gene of HIV-1 strain SF-2",* lNSTITUT PASTEUR claims that the 98 probes in question bind to the HIV-1 virus base sequence between 2085 and 5098 in the HXB2 nomenclature (i.e., according to the patent numbering, between 1555 and 4568) and corresponding to the *pol* gene region ,'

In support of his argument, he also submits a report drawn up on May 30, 2008 by Dr. Jacques-H.M. COHEN, who, after analyzing the disputed kit, concludes in the following terms: *"All the fragments tested from the pol gene give a positive signal in the Versant HIV-1 RNA 3.0 kit, while the fragments from the env gene give no signal. (...) The branched bDNA probes in the Versant HIV-1 RNA 3.0 kit (bDNA) 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 obtainable from any DNA fragment conforming to the invention",* He concludes that the DNA fragments covered by claim 5 - corresponding to DNA between 3500 and 6500 (i.e. 4030 to 7030 in the HBX2 nomenclature) - and the DNA fragments covered by claim 6 - corresponding to DNA between 800 and 3500 (i.e. 1330 to 4030 in the HBX2 nomenclature) - *"largely"* cover the *pol* gene identified by the *Versant HIV-1 RNA 3* assay.*0 Assay (bDNA),*

That the probes used in the kits marketed by SIEMENS are therefore identical to the probes protected by claim 7, including insofar as they depend on claims 5 and 6,

That adding that detection is obtained in the incriminated test by incubation of the complex with a chemiluminescent substrate - which is in no way disputed - the INSTITUT PASTEUR concludes that the process taught by claim 8 of the patent is reproduced which, as previously explained, covers a process comprising a first step of hybridization of target probes, as defined in claim 7, to viral RNA and a second step of hybridization of target probes, as defined in claim 7, to viral RNA.

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detection of hybridized probe ;

But whereas it was previously indicated in the discussion of the scope of European patent no. 0 178 978 that claims 5 and 6 - which relate to "a *nested DNA gainer whose sequence corresponds to that part of M19 DNA which extends approximately",* in the case of claim 5, *"from the Kpn I site (3500) to the Bgl II site (6500) approximately", and in* the case of claim 6, "from the *Pst I site (800) to the Kpn I site (3500) approximately" - are to be interpreted as* relating to fragments of *M19 DNA,* and with regard to claim 6, *"from the Pst I (800) site to the Kpn I (3500) site approximately" -* are to be interpreted as referring to cloned DNA fragments defined by their restriction sites and characterized by their ends, size and position on the viral genome as contained in clone XJI9 ;

Whereas it follows from the above-mentioned data sheet that the target probes and capture probes used in the *Versant HIV*- kit *1 RNA 3.0 Assay (bDNA)* are synthetic oligonucleotides, not cloned DNA;

Furthermore, the 98 probes in question - i.e. 17 capture probes and 81 target probes, each consisting of around 20 to 30 bases, as described above - even assuming that they are placed end-to-end, bind to the HIV-1 virus base sequence between 2085 and 5098 in the HXB2 nomenclature (i.e., according to the patent numbering, between 1555 and 4568) and are therefore not positioned on the fragment of claim 5 corresponding to DNA between 3500 and 6500 (i.e., 4030 to 7030 in the HBX2 nomenclature), nor on the fragment of claim 6 corresponding to DNA between 800 and 3500 (i.e., 1330 to 4030 in the HBX2 nomenclature),

It follows that the fragments making up the probes in question do not identically reproduce the characteristics of claims 5 and 6 of the patent, which, as rightly argued in the defense, are independent of each other and cannot be combined to assess infringement;

That claim 7, which covers a *"probe for the in vitro detection of LAV consisting of a DNA according to any one of claims 1 to* 'f', is no more reproduced since it is directly dependent on claims 5 and 6, for which infringement has been ruled out;

Similarly, claim 8, which relates to a *"method for the in vitro detection of viral infection due to LAV viruses, comprising contacting a biological sample from a person in whom LAV infection is to be detected and containing RNA in a form suitable for hybridization with the probe of claim 7 under hybridizing conditions, and detection of the hybridized probe"* and which, as stated above, is limited to a process involving the use of probes composed of cloned DNA fragments corresponding to the retroviral genome contained in clone XJ19, is not infringed for lack of reproduction of claims 5, 6 and 7 on which it depends;

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Whereas INSTITUT PASTEUR argues, in the alternative, that the use as probes of complete fragments of 2700 bases (claim 6) or 3000 bases (claim 5) is infringed by equivalence through the use, in kits marketed by SIEMENS, of probes which cover, wholly or in part, these sequences and perform the same new DNA-RNA hybridization function in order to obtain a similar result consisting in the detection of the hybridized probe with a view to diagnosing the disease ;

However, it has just been recalled that claim 8 does not protect, as claimed by the applicant, a new general means of detecting and quantifying the AIDS virus by hybridizing DNA probes labeled with viral RNA - such a detection method having already been disclosed in the European patent application filed on August 19, 1985 by the NIH under the priority of US patent 643306 of August 22, 1984 - , but, in view of the restrictions placed by the patentee on the text of the claims during examination and opposition proceedings before the European Patent Office, a process involving the use of probes composed of cloned DNA fragments corresponding to the retroviral genome contained in clone ZJ19 ;

It follows that the patented method, i.e. the use of probes consisting of DNA fragments, is only new in its form, the function of hybridization with viral RNA with a view to detecting the disease it causes being known;

That infringement by equivalence, which in the present case cannot therefore result from the identity of functions, can therefore only be constituted if the very form of the patented means is reproduced, in an equivalent form, and in what characterizes its patentability, namely in the present case probes consisting of cloned DNA fragments defined by their restriction sites and corresponding to the retroviral genome contained in clone ZJ19 ;

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

That infringement by equivalence can therefore no longer be accepted;

Whereas INSTITUT PASTEUR will consequently have its claims for infringement of claims 5, 6, 7 and 8 of European patent no. 0 178 978 dismissed, without needing to have recourse to the provisions of article L.615-5-1 of the French Intellectual Property Code. of the French Intellectual Property Code, the reversal of the burden of proof from which he intends to benefit being irrelevant in this case, since the rejection of his claims results not from his difficulties in proving the alleged infringement, but from the absence of infringement.

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** Infringement of claim 11 by supply of means*

Whereas according to article L.613-4, lº of the French Intellectual Property Code, *"In the absence of the consent of the owner of the patent, it is also prohibited to deliver or offer to deliver, on French territory, to a person other than those entitled to exploit the patented invention, the means for implementing, on this territory, this invention relating to an essential element thereof, when the third party knows or when the circumstances make it obvious that these means are suitable or intended for this implementation",*

Whereas claim 11 of European patent no. 0 178 978 covers *"purified RNA of LAV virus having a size of 9.1 to 9.2 kb and corresponding to the complementary DNA contained in W19 (CNCM 1-338)". ,*

That lNSTITUT PASTEUR considers that the various items seized during the seizure and counterfeiting operations establish that the complete genomic RNA of the AIDS virus is purified - or released - during the *Versant HIV-1 RNA 3.0 Assay (bDNA),* its data sheet specifying that *"HIV-1 is first concentrated by centrifugation from plasma"* and that *"once the genomic RNA has been released from the virions, it is captured on a solid support using Capture Probes",*

It follows that the supply by SIEMENS of kits containing the reagents, specific means and experimental protocol for isolating the viral RNA present in the infectious viral particles found in patients, and the provision of instructions for use, constitute acts of delivery of the means for implementing the invention relating to an essential element thereof, namely the viral RNA of the HIV-1 virus covered by claim 11;

It should be remembered that, in accordance with the aforementioned provisions, the supply of means only constitutes an act of infringement on condition that the means supplied - which, as is rightly claimed in the application, are not necessarily claimed in themselves - relate to an essential element of the invention, thus participating in its result;

Consequently, SIEMENS cannot rely on the fact that claim 11 is a product claim and not a process claim to conclude that the quantification kits at issue do not relate to a constituent element of the claim, since such a circumstance alone is not such as to exclude infringement by supply of means;

However, it has been said that claim 11 must be interpreted as relating not to the entire genome of the virus responsible for AIDS, but to a strand of RNA precisely defined, on the one hand by its size, and on the other hand by its ability to hybridize with the complementary DNA contained in XJ19, even though Professor

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MONTAGNIER testifies in these proceedings, without being contradicted, that "it *was from the DNA contained in M19 that we were then able to sequence the entire HIV-1 genome". ,*

Whereas it has indeed been established, without the need for expert appraisal, that the complete viral RNA found in patients' blood samples is used in the implementation of the allegedly infringing quantification kits, it has in no way been demonstrated, or even alleged, that these kits enable the precise isolation of virus RNA with a size of
9.1 to 9.2 kb and corresponding to the complementary DNA contained in clone ZJ19, i.e. an RNA with ends corresponding to those of U19 DNA,

Whereas INSTITUT PASTEUR's claim for infringement by supply of means of claim 11 of European patent no. 0 178 978 will therefore be dismissed.

- On the counterclaim for damages for abuse of process

Whereas the exercise of a legal action constitutes, in principle, a right and only in the case of malice, bad faith, or a gross error equipollent to fraud, does it degenerate into an abuse that can give rise to a debt of damages;

That the defendant company's claim in this respect will be dismissed, in the absence of proof of any intent to harm or recklessness on the part of INSTITUT PASTEUR, which may have misunderstood the extent of its rights, and of any prejudice other than that suffered as a result of the defense costs incurred.

- Other requests

Whereas L'INSTITUT PASTEUR, plaintiff, should be ordered to pay the costs, which will be recovered in accordance with the provisions of article 699 of the French Code of Civil Procedure;

In addition, it must be ordered to pay SIEMENS, which has incurred irreducible costs in asserting its rights, compensation under article 700 of the French Code of Civil Procedure, which it is fair to set at the sum of 150,000 euros,

Whereas provisional execution is not applicable and cannot be ordered.

THEREFORE

The Court of First Instance, ruling in public, by means of a contradictory judgement and delivered at first instance,

- DISMISSES all INSTITUT PASTEUR's claims;

- DISMISSES SIEMENS HEALTHCARE DIAGNOSTICS from

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his counterclaim for damages for abuse of process;

- ORDERS INSTITUT PASTEUR to pay SIEMENS HEALTHCARE DIACiNOSTICS the sum of 150,000 euros pursuant to article 700 of the French Code of Civil Procedure;

- ORDERS INSTITUT PASTEUR to pay the costs, which will be recovered in accordance with the provisions of article 699 of the French Code of Civil Procedure;

- DIT n'y avoir lieu aluprof provisional execution.

Fait et jugé " RIàTA28 lemai 2010.

Vi Greffier

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p/The Président