Decisions*

Patent Law

FRANCE

European Patent Convention, Art. 69 – "In Vitro Detection of HIV Infection II"

Patent claim for a method for the in vitro detection of viral infection due to LAV (HIV) covers only a method using the probes mentioned in the patent claims, namely probes containing DNA sequences characterized by their restriction sites, their position on the viral genome and their correspondence to the deposited clone; the claim thus does not cover any method for the in vitro detection of HIV in which a DNA probe hybridizes with viral RNA.

The action for infringement of the method claim is dismissed because the plaintiff does not provide evidence of the alleged infringement.

The action for contributory infringement of a patent claim covering purified RNA is dismissed because the diagnostic kits containing a purification step, supplied by the defendant, did not relate to an element of the patent claim and were not suited for putting the invention into effect.

Decision of the Paris Court of Appeal (Cour d'appel)
(4th Chamber, Section A)
4 March 2009 Case No. 07/08437
Institut Pasteur v. S.A.S. Chiron Healthcare and Chiron Healthcare Ireland Ltd

Facts:

Considering the appeal lodged on 14 May 2007 by Institut Pasteur against a judgment handed down on 7 February 2007 by the Paris District Court,[1] which, dismissing its claims, ordered it to pay Chiron compensation of € 45,000 pursuant to Art. 700 of the French Code of Civil Procedure and to pay the costs.

Considering the last pleadings dated 17 October 2008, by way of which Institut Pasteur, seeking the reversal of the appealed judgment in that it did not consider:

- the pioneer nature of the inventions protected by European patent No. 0 178 978,
- that claim 11 of European patent No. 0 178 978 covers the whole specific genomic RNA of HIV-1, causing AIDS,
- that the charge for infringement of claim 11 of European patent No. 0 178 978 was well-founded,
- that claim 8 of European patent No. 0 178 978 covers the general means characterized by the use of the RNA of the AIDS virus for detecting the viral infection by a viral RNA-DNA hybridization,

* Where indicated by an asterisk (*), headnotes are official. Those without an asterisk are editors' headnotes.

1 *See* 38 IIC 981 (2007).

- that the charge for infringement of claim 8 of European patent No. 178 978 was well-founded.

It requests the court of appeal, ruling on again, to hold that Chiron Healthcare SAS and Chiron Healthcare Ireland Limited are liable for infringement of claims 8 and 11 of European patent No. 0 178 978, consequently, as main request, to hold that claim 8 is infringed by equivalence by Chiron Healthcare SAS and Chiron Healthcare Ireland Limited, which offer in France Procleix assays implementing said claim; to hold that claim 8 is also infringed by the supply of means for implementing the method covered by claim 8; to hold that claim 11 is infringed by supply of means.

In the alternative, to appoint an expert in charge of determining if:

- the capture oligonucleotides and the promoter primers supplied by Chiron Healthcare SAS and Chiron Healthcare Ireland Limited hybridize with the released viral RNA, during the implementation of the Procleix assay, for diagnosing the infection by HIV-1,
- the isolated and purified RNA, as defined in the asserted claim 11, is identical to the viral RNA released during the implementation of the target capture defined by the Procleix assays.

Further to order Chiron Healthcare SAS and Chiron Healthcare Ireland Limited to exhibit all the material elements for the performance of these expert investigations, and to order Chiron Healthcare SAS and Chiron Healthcare Ireland Limited to leave access to any type of equipment or material for the performance of these expert investigations.

As the main request: to dismiss the counterclaim lodged by Chiron Healthcare SAS and Chiron Healthcare Ireland Limited for abusive appeal and to order Chiron Healthcare SAS and Chiron Healthcare Ireland Limited to pay, as an advance payment, € 8 million for the total compensation, to appoint any expert with a mission:

- being provided with all the documents justifying the offers for sale and sales recorded in France by Chiron Healthcare SAS and Chiron Healthcare Ireland Limited regarding the Procleix assay and the equipment required for implementing said assay,
- assessing the damage suffered by taking into account the royalty rates applied in this high-technology field,
- to authorize the publication of the judgment to be handed down in 10 newspapers or magazines of Institut Pasteur's choice without the cost for all the insertions exceeding € 100,000,
- to order Chiron Healthcare SAS and Chiron Healthcare Ireland Limited to pay € 130,000 pursuant to Art. 700 of the French Code of Civil Procedure and to pay the costs of first instance and appeal proceedings.

Considering the last pleadings dated 3 December 2008, in which Chiron Healthcare SAS and Chiron Healthcare Ireland Limited request the court of appeal, as main request, to affirm the judgment of the Paris District Court of 7 February 2007 in that it dismissed Institut Pasteur's claims for infringement of patent No. 0 178 978 on the following grounds:

- claim 8 cannot be construed, as alleged by Institut Pasteur, as to cover any method for the in vitro detection of viral infection due to the LAV virus 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 a DNA probe, such as one of those contained in claim 7, under hybridizing conditions and detecting the hybridized probe; this claim however covers only a method for detection using a probe according to claim 7,

- therefore, by importing and marketing their diagnostic kit, Chiron does not provide the means for implementing claim 8 of patent No. 0 178 978,
- by importing and marketing their diagnostic kit, Chiron does not infringe claim 11 on the grounds of supply of means, since the diagnostic kit does not relate to an element of claim 11.

In the alternative:

On Patent Claim 8

- should claim 8 be construed, as alleged by Institut Pasteur, to cover a method for the in vitro detection of viral infection due to the LAV virus 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 any type of DNA probe], under hybridizing conditions and detecting the hybridized probe: to hold that this claim is invalid for lack of novelty or inventive step.

On Patent Claim 11

- should it be held that claim 11 can be infringed even if the detection kit does not include any element of this claim: to hold that patent claim 11 cannot be construed, as alleged by Institut Pasteur, to cover any purified RNA of the LAV virus which size would be superior to 9.2 kb and independently to know if it corresponds to the complementary DNA contained in λ-J19,
- to hold that by importing and marketing their diagnostic kit, they do not supply the means for implementing claim 11,
- in the alternative, should claim 11 be construed, as alleged by Institut Pasteur, to hold that this claim is invalid for lack of novelty.

In any case:

- to hold that the appeal lodged by Institut Pasteur is abusive,
- to order Institut Pasteur to pay a sum of € 200,000 as damages for abusive proceedings, a sum of € 300,000 pursuant to Art. 700 of the French Code of Civil Procedure,
- to order Institut Pasteur to pay all the costs.

Whereupon, the court of appeal, considering that, for a thorough presentation of the facts and of the proceedings, it is expressly referred to the appealed judgment and to the parties' pleadings, that it is sufficient to recall that:

- Institut Pasteur is a foundation involved in research in microbiology,
- Chiron Healthcare SAS and Chiron Healthcare Ireland Limited, companies governed by the laws of the United States, which specialize in biotechnology, manufacture and market vaccines, therapeutic products and blood diagnostic tools,
- in the 1980s, several public research organizations worked on the identification of the AIDS virus, notably the CNRS and Institut Pasteur directed by Professor Montagnier, the NIH which depends on the United States Department of Health, directed by Professor Gallo, the group Chiron on the basis of the work of Professor Levy of the University of San Francisco,
- in 1984, these organizations isolated this virus which was called LAV (Lymphadenopathy Associated Virus) by Professor Montagnier, HTLV-III (Human T-cell Lymphotropic Virus-III) by Professor Gallo and ARV (AIDS-Associated Retroviruses) by Professor Levy,
- this virus was called HIV in 1986,
- following these discoveries, the various research organizations filed different patents to protect the identified parts of the HIV genome as well as their use, in particular for the detection of the virus:

  a) European patent No. 0 173 529 filed by the NIH on 19 August

1985 under the priority of a US patent application No. 643,306 dated 22 August 1984,[2]

b) European patent filed by Institut Pasteur on 17 September 1985 under the priority of a British patent No. 8423659 dated 19 September 1984, granted on 6 February 1991 under No. 0 178 978, entitled "Cloned DNA sequences, hybridizable with genomic RNA of lymphadenopathy-associated virus (LAV)",

c) European patent No. 0 181 150 filed by Chiron Corporation on 30 October 1985 under the priority of US patent application Nos. 667,501 of 31 October 1984 and 696,534 of 30 January 1985,

- DNA fragments corresponding to the HIV clones sequenced and described in these patents were deposited in collections pursuant to the Budapest Treaty,
- clones called BH10, BH5 and BH8 were deposited by the NIH on 30 July 1984; clones λ-J19 and λ-J81 were deposited by Institut Pasteur on 11 September 1984, clones λ-ARV-2 were deposited by Chiron Corporation on 26 October 1984,
- reproaching the companies of the group Chiron to have marketed HIV detection kits under the name Procleix since September 1999, constituting, according to it, the means of implementation of claims 8 and 11 of its patent, duly authorized by an order of the Presiding Judge, Institut Pasteur performed a *saisie-contrefaçon* on 12 July 2005,
- these were the circumstances under which Institut Pasteur served a summons for infringement upon Chiron Healthcare SAS and Chiron Healthcare Ireland Limited before the Paris District Court.

On the Patent

Considering that European patent No. 0 178 978, filed on 17 September 1985 by Institut Pasteur, under British priority of 19 September 1984, granted on 6 February 1991, was the subject-matter of an opposition procedure before the European Patent Office (EPO) by Chiron Corporation and was maintained with amended claims by way of a decision of the Board of Appeal on 18 November 1999, the invention, entitled "Cloned DNA sequences, hybridizable with genomic RNA of lymphadenopathy-associated virus (LAV)", relates to cloned DNA sequences hybridizable to genomic RNA and DNA of lymphadenopathy-associated virus (LAV), to a process for the preparation of said sequences and to their uses, more particularly to stable probes containing related viruses or DNA proviruses in any medium, in particular in biological samples containing any of them.

The patentee recalls that viruses analogous to LAV have been isolated from patients with AIDS or pre-AIDS, that these viruses, called HTLV-III and ARV Cloned DNA sequences, hybridizable with genomic RNA of lymphadenopathy-associated virus (LAV) and ARV, show many characteristics similar to those of LAV and represent independent isolates of the LAV prototype and that for ease of language, they will all be referred to as LAV. It sets out that the detection methods available today are based on the recognition of viral proteins, that such a method is described in the patent application EP-A-0 138 667, entitled antigens, means and method for the diagnosis of lymphadenopathy and acquired immune depression syndrome, filed on 14 September 1984, under the priority of patent application No. 8324800 filed on 15 September 1983, that this European patent application describes different recombinant clones of HTLV-III. It argues that the invention aims at providing new means which should not only be useful for the

2 Translator's note: 2004 in the French text.

detection of LAV or related viruses, but also have more versatility, particularly in detecting specific parts of the genomic DNA of said viruses, whose expression products are not always detectable by immunological methods.

The patent comprises 11 claims thus worded:

Claim 1: A cloned DNA which contains a DNA corresponding to the LAV retroviral genome contained in λ-J19 (CNCM I-338), said cloned DNA including LTR elements U3, R, and U5 of said retroviral genome,

Claim 2: The DNA of claim 1 which is a cDNA,

Claim 3: A cloned DNA which contains a DNA which consists:

- either of a 3' terminal fragment of the DNA contained in λ-J19 (CNCM I-338) corresponding to the LAV retroviral genome, and which has up to 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, Kpn I, Xho I, Bam HI, Hind III, Bgl II,

Claim 4: A cloned DNA fragment whose sequence corresponds to the part of the DNA of λ-J19, which extends from approximately Kpn I (6100) to approximately Bam HI (8150) thereof,

Claim 5: A cloned DNA fragment whose sequence corresponds to the part of the DNA of λ-J19, which extends from approximately Kpn I (3500) to approximately Bgl II (6500) thereof,

Claim 6: A cloned DNA fragment whose sequence corresponds to the part of the DNA of λ-J19, which extends from approximately Pst I (800) to approximately Kpn I (3500) thereof,

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

Claim 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,

Claim 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,

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

Claim 11: The purified RNA of LAV virus which has a size from 9.1 to 9.2 kb and which corresponds to the complementary DNA contained in λ-J19 (CNCM I-338);

Considering that Institut Pasteur asserts claims 8 and 11 of this document.

On the Scope of Patent Claims 8 and 11

Considering that Institut Pasteur contends that the accused Procleix assay provides, pursuant to Art. L. 613-4 of the French Intellectual Property Code, all the means of implementation permitting the isolation of the RNA covered by claim 11, before providing those of the method permitting the in vitro detection of a viral infection due to the LAV virus or HIV-1, which are covered by claim 8 of said patent.

Therefore, setting out that the characterization and the possibility to use the RNA genome of the virus causing AIDS is a prerequisite necessary to the implementation of the diagnosis method covered by patent claim 8, Institut Pasteur first asserts claim 11 which protects the purified RNA of the virus which has a size from 9.1 to 9.2 kb and which corre-

sponds to the complementary DNA contained in λ-J19 (CNCM I-338).

The parties are opposed with regard to the scope of patent claims 8 and 11.

In patent law, pursuant to Art. 69 of the Munich Convention, the extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

Institut Pasteur contends that patent No. 0 178 978 constitutes a premier innovation making this patent a pioneering one, so that, according to it, claims 8 and 11 have a scope going beyond their literal meaning.

However, if in the presence of a pioneer invention, the patent may describe one embodiment of the invention and claim any other possible embodiment, on the other hand, even a pioneer patent cannot be granted a general scope if its claims are drafted using restrictive wording.

A non-ambiguous claim with a narrow scope cannot be granted a general scope on the pretext of an interpretation when, in particular, the patentee was forced to limit the scope of the claim during the grant and opposition procedures in order to be distinguished from the prior art.

However, in the present case, it is established that the patent application was initially filed with 24 claims and that, following the opposition procedure initiated by Chiron Corporation which gave rise to a ruling in first instance on 9 August 1994 and to a decision in appeal of the EPO Board of Appeal on 18 November 1994, the granted patent comprises 11 claims of a limited scope.

On Claim 11

Considering that claim 11 as filed related to the purified RNAs of LAV viruses which have sizes from 9.1 to 9.2 kb, once amended, it protects the purified RNA of LAV virus which has a size from 9.1 to 9.2 kb and which corresponds to the complementary DNA contained in λ-J19 (CNCM I-338).

Institut Pasteur, stating that none of the prior art documents justifies a strict reading of this claim, nevertheless alleges that it protects, independently of the clone λ-J19, the specific nature of the claimed sequence, the whole purified RNA genome of the LAV virus or HIV-1, an essential compound to the implementation of the protocol for detecting the virus in a biological sample to be tested.

However, the patentee, which amended its claims to confer them a restricted scope, cannot, without damaging the security of third parties, allege that the amendments were not necessary, that the restricted claims would have the same scope as the initial broader claims and that the prior art documents having motivated the amendments would not be relevant.

Institut Pasteur contends that the complementary DNA (cDNA), to which claim 11 refers, corresponds to the reflection of the RNA genome of the LAV virus (or HIV-1) and cannot be mistaken for the proviral DNA described in the European patent application No. 0 173 529[3] filed on 22 August 1984 by the NIH.

Although it is not disputed that the clones described in these documents were produced in different ways, it remains that in both cases, the clone which was produced and described is composed of the double-strand DNA corresponding to the viral genome of the HIV.

Under these circumstances, the NIH patent, which discloses the restriction sites of the HIV DNA partly anticipates Institut Pasteur's patent, regardless of the suggestion of the presence of a pX gene, which does not belong to the HIV genome.

3 Translator's note: US patent application in the French text.

Furthermore, on 31 August 1984, the researchers of Professor Gallo's team published the result of their research in the magazine "Science". This article called "the Arya, Gallo article" discloses a general method permitting to purify the HIV RNA from an AIDS patient's blood and teaches that the isolated RNA strands, which have a size of approximately 9 kb, comprise the whole R region at each polyA tail[4].

It results from the foregoing that the only feature distinguishing claim 11 at issue is the specific nature of the claimed strand, namely its size from approximately 9.1 to 9.2 kb and its ability to hybridize with the cDNA contained in the clone λ-J19.

On Claim 8

Considering that Institut Pasteur contends that patent claim 8 relates to a method for the in vitro detection of viral infection due to the LAV virus which comprises contacting a biological sample originating from a patient suspected of being infected with the LAV (HIV-1), said sample containing RNA in a form suitable for hybridization with the probe of claim 7 under hybridizing conditions and detecting the hybridized probe.

It alleges that the method covered by this claim protects a novel general means for the detection of the viral charge of AIDS characterized by the hybridization of DNA probes with the viral RNA and that it cannot be limited by the choice of the probe according to claim 7.

Recalling the terms of claim 8 thus worded: "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", it should be noticed that the method comprises two steps: on the one hand, contacting under hybridizing conditions a biological sample originating from a person infected by LAV and containing RNA in a form suitable for hybridization with the probe of claim 7 and on the other hand, the detection of the hybridized probe.

It should be noted that the amendments, which were made by Institut Pasteur during the examination procedure, led to the limitation of the scope of claim 8 in that it requires using the probe, the subject-matter of claim 7, which depends on claims 1–6 protecting cloned DNA fragments defined by their restriction sites and corresponding to the retroviral genome contained in λ-J19.

This construction is confirmed by the description referring to (page 17, lines 27 et seq. page 18, lines 10 et seq.) DNA fragments according to the invention and does not describe the general means of probes.

It belonged to Institut Pasteur, during the examination and opposition procedures, to amend the process claim or the probe claims in order to dissociate them from the fragment claims.

Institut Pasteur cannot contend that claim 8 would cover any diagnostic method, whichever the probe used, on the ground that this claim would indirectly refer to claim 1, which, because of the use of the word "corresponding", would continue to cover any DNA fragment.

Indeed, the Board of Appeal of the EPO, with regard to claim 1, recalled that the word "corresponding" appears to be in the narrow sense of base-to-base correspondence, subject to the allowable variations which would not substantially alter their capability of also hybridizing with the LAV retroviral genomes, as understood by a person skilled in the art.

4 Translator's note: should read "comprise the whole R region at each end and a polyA tail".

Thus, without distorting this decision, it cannot be alleged that the protection of the allowable variations would also extend to the protection of all equivalent DNA fragments.

It follows, recalling if necessary that the article published by the researchers of the Nih, Arya and Gallo, before the priority date of the patent, already taught the detection of an infection due to the HIV by using labelled probes, that claim 1 covering the cloned DNA contained in λ-J19 and any identical cloned DNA does not protect in any way any DNA fragment, so that claim 8 cannot relate to any diagnostic method regardless of the type of probe used.

Therefore, the scope of claim 8 is limited to a detection method involving the use of probes composed of cloned fragments and including a DNA fragment corresponding to the retroviral genome contained in λ-J19.

The scope of claims 8 and 11 of the asserted patent being thus defined, there is no reason to examine the alternative request for invalidity of these claims lodged by Chiron Healthcare SAS and Chiron Healthcare Ireland Limited which do not dispute their validity as modified after opposition and as construed.

On the Infringement of Claims 8 and 11

Considering that Institut Pasteur, which reproaches to Chiron for committing acts of infringement, sets out that the accused Procleix assay comprising three steps (a step of isolation of the viral RNA, a step of amplification of the viral RNA and a step of detection of the products resulting from this amplification), provides the means of implementation of claims 8 and 11 of the asserted patent by equivalence.

Considering from a legal point of view that, pursuant to the provisions of Art. L. 613-4 of the French Intellectual Property Code, it shall 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 exploit 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 suitable for putting and are intended to put the invention into effect.

Institut Pasteur does not deny Chiron's explanations with regard to the implementation method of this kit, namely:

- capturing target RNAs, which consists in releasing the viral RNAs by cell lysis and capturing the latter by means of capture oligonucleotides which hybridize with target RNAs and are attached to magnetic micro particles,
- a washing step to remove plasma components and nucleic acids other than those fixed to the capture oligonucleotides, it being pointed out that these capture oligonucleotides are synthetic sequences composed partly of DNA and RNA,
- an amplification step implementing the amplification primers, using two primers composed of synthetic oligonucleotides whose function is to initiate the reverse transcription and polymerase steps, the promoter primer including a zone called "promoter 7" necessary for the function of RNA polymerase,
- a detection step consisting in hybridizing the amplified RNA with probes labelled with a luminescent substance, two viral probes, one internal control probe, composed of synthetic oligonucleotides, very short (each smaller than 25 nucleotides) and non-contiguous, positioned in several places of the genome,
- an incubation phase during which the probes hybridize with the antisense amplified RNA,

– the captured viral RNA is the whole viral genome, comprising the entire R region at each end, to which the polyA tail is joined, this isolated RNA being described in the aforementioned Arya, Gallo article.

On Claim 8

Considering that the accused detection kit uses three types of oligonucleotides hybridizable with genetic material: the capture oligonucleotides, two promoter primers during the amplification step, two labelled probes during the detection step, Institut Pasteur alleges that the capture oligonucleotides and the promoter primers constitute means of implementation of claim 8, which covers, according to it, a novel general means consisting in using DNA probes hybridizable with the genomic RNA for the detection of the viral infection by hybridizing viral RNA with DNA.

It adds that these oligonucleotides and these primers are means equivalent to the probes referred to in the asserted claim. However, it results from the foregoing that the scope of claim 8 is limited to a detection method involving the use of the probe, the subject-matter of claim 7, which depends on claims 1 to 6 protecting cloned DNA fragments defined by their restriction sites and corresponding to the retroviral genome contained in λ-J19.

It should be noted that Institut Pasteur does not contend at all that Chiron's detection kit uses the probes of claim 7, composed of fragments of claims 1–6. Institut Pasteur neither shows the implementation of the other characteristics of claim 8.

Indeed, the capture oligonucleotides and the primers of Chiron's detection kits are synthetic, so that they cannot fall within the scope of the patent teaching cloned DNA fragments. These oligonucleotides are not DNA probes but chimerical oligonucleotides composed of DNA for one part and of RNA for the second part, the part hybridizing with the HIV RNA being composed of RNA, which can be produced only by chemical synthesis and not by cloning. Nor do the promoter primers constitute probes of claim 8 since they include a promoter "T7" area necessary to the function of RNA polymerase which is not found in the retroviral genome contained in λ-J19.

Institut Pasteur cannot use the doctrine of equivalents, since claim 8 does not cover the general means of hybridization but the specific means of hybridization of viral RNA with a probe composed of a DNA fragment which corresponds to the genome contained in the clone λ-J19; therefore, the appealed judgment, dismissing the charge for infringement of claim 8, will be affirmed.

On Claim 11

Considering that Institut Pasteur contends that Chiron's diagnostic assay infringes claim 11 by the supply of means since, according to it, the use of this assay results in the isolation of the RNA of HIV-1, the supply of means constitutes an act of infringement only if the supplied means relate to an essential element of the invention, namely, taking part in the result of the latter.

In the present case, it should be noted that patent claim 11, as amended, relates to 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 λ-J19. On the one hand, this claim does not cover a method but a product; on the other hand, it does not characterize the RNA in that it contains all the genetic information necessary to reconstitute the whole genome but in that it defines the RNA which corresponds to the cDNA of λ-J19.

It is not proven at all that implementing this kit would permit the isolation of the specific RNA fragment corresponding to the complementary DNA contained in λ-J19. It is not denied that the RNA isolated by Chiron's kits has a size superior

to 9.2 kb and contains a complete R sequence at each of its ends, so that it does not fall within the scope of claim 11. Therefore, the appealed judgment, dismissing Institut Pasteur's requests for infringement, is worth to be affirmed.

On the Other Requests.

Considering that initiating a court action, like exercising the right to appeal, turns into an abuse giving rise to a claim for damages only in the case of malice, bad faith, gross mistake equipollent to deceit or blameful lack of heed; these requirements are not met in the present case. The counterclaim lodged by Chiron Healthcare SAS and Chiron Healthcare Ireland Limited will be dismissed.

It emerges from the outcome of the decision that Institut Pasteur cannot benefit from the provisions of Article 700 of the French Code of Civil Procedure; on the other hand, equity demands that it be ordered, on the same ground, to pay Chiron Healthcare SAS and Chiron Healthcare Ireland Limited the additional sum of € 130,000.

The court of appeal affirms all the orders of the appealed judgment, and adding thereto orders Institut Pasteur to pay Chiron Healthcare SAS and Chiron Healthcare Ireland Limited the additional sum of € 130,000 for the unrecoverable costs of the appeal proceedings, dismisses all the other requests, and orders Institut Pasteur to pay the costs and holds that these costs can be collected pursuant to the provisions of Art. 699 of the French Code of Civil Procedure.

Comment:

The French research organization, Institut Pasteur, filed European patent No. 0 178 978 on 17 September 1985, under British priority of 19 September 1984 for "cloned DNA sequences, hybridisable with genomic RNA of lymphadenopathy-associated virus (LAV)" the virus causing AIDS, now known as HIV. Most of the claims of this patent had been amended before the EPO, during examination or opposition proceedings, particularly in light of European patent No. 0 173 529 filed by the NIH on 19 August 1985 under the priority of the US patent application of 22 August 1984, published on 5 March 1986, and thus relevant for novelty considerations only.

Chiron Blood Testing SAS and Chiron Healthcare Ireland Limited were offering for sale diagnostic kits for the detection of HIV in blood samples. Institut Pasteur argued that these companies directly infringed claim 8 of its patent and indirectly infringed (i.e. contributory infringement) claim 11. It initiated proceedings on 25 July 2005, just three months before the expiry of its patent, and requested payment of an interim payment of € 8 million as an account on damages.

Claim 1 of patent No. 0 178 978 relates to cloned DNA corresponding to the HIV retroviral genome contained in the deposited clone and characterized by its size. Claims 2 and 6 relate to cloned DNA fragments of the same deposited DNA, characterized by their restriction sites and their position on the genome.

Claim 7 covers a probe for the in vitro detection of viral infection by HIV, which consists of a DNA according to any of claims 1–6.

Claim 8 "Covers a method for the in vitro detection of viral infection due to the LAV virus 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".

Claim 11 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 lambda-J19 (CNCM I-338)."

On 7 February 2007, the Paris District Court dismissed the claims of Institut Pasteur on the ground that the detection kits of the Chiron companies did not fall within the scope of the patent and that their sale did not amount to contributory infringement.[5] Institut Pasteur lodged an appeal against the first instance decision seeking the reversal of the judgment.

Arguments of the Parties

The appellant, Institut Pasteur, alleged that its patent is a pioneer invention and that claim 8 covers a general method for the in vitro detection of HIV, i.e. any method enabling the detection of AIDS, characterized by the hybridization of DNA probes with viral RNA. It therefore claimed that the sale of Chiron's detection kit infringed claim 8 of its patent. Institut Pasteur further claimed that claim 11 covers any purified RNA sequence of HIV, whatever its size and irrespective whether it corresponds to the cDNA of the deposited clone. It thus argued that Chiron indirectly infringed claim 11 of its patent by supplying the means relating to an essential element of that claim.

The respondent, Chiron, argued to the contrary that claims 8 and 11 could not be construed broadly. Specifically, Chiron argued that:

- claim 8 relates to a specific method using the probes of claim 7, namely probes consisting of the cloned DNA fragments of claims 1–6;
- claim 11 covers the specific isolated RNA sequence corresponding to the cDNA of the deposited clone.

Chiron further submitted that, should the patent be construed differently, claims 8 and 11 would be invalid in view of the prior art. It requested the appeal court to affirm the decision issued by the Paris District Court and to dismiss Institut Pasteur's action for infringement of claim 8 on the ground that the plaintiff did not demonstrate that the accused detection kit would use the probes of claim 7 consisting of the cloned DNA fragments of claims 1–6 and claimed, on the contrary, that the probes used in their detection kit differ from those referred to in claim 8. Chiron argued that the marketing of the detection kits could not have amounted to contributory infringement of claim 11 since the means supplied did not relate to an element of this claim and were not suited to carry out the invention, namely to isolate the specific viral RNA of claim 11.

Findings of the Paris Court of Appeal

The appeal court first reminded the rules governing the scope of protection conferred by a patent. It then reviewed:

- the scope of Institut Pasteur's patent No. 0 178 978, and
- the alleged infringement of those claims.

While assessing the scope of claim 8, the appeal court studied the prior art relied on by Chiron.

Scope of the Protection Conferred by a Patent

The appeal court first reminded the rules governing the scope of protection conferred by a patent, then applied them to Institut Pasteur's patent claims 8 and 11. The court began by quoting Art. 69 EPC. It reached the conclusion that these claims have a scope corresponding to their literal wording, and not the extensive scope requested by Institut Pasteur. The court explained that:

- the extent of the protection conferred by a patent shall be determined by the wording of the claims;
- this rule applies even to a pioneer patent, which can have a general scope only if the claims are drafted broadly; in other words, even a pio-

5 *See* 38 IIC 981 (2007).

neer patent cannot be granted a broad scope if the claims have a narrow wording.

Interestingly, the appeal court took into consideration the changes made by Institut Pasteur to its patent during the examination and opposition proceedings to assess the scope of the patent. It held that patent interpretation cannot serve as a pretext to give a broad construction to clear claims which have been amended during the examination and opposition procedures before EPO to be distinguished from the prior art. The court thus dismissed Institut Pasteur's contention that, because its patent is a pioneer patent, it should be granted a broad scope, irrespective of the wording of the claims. It then applied these rules to claims 8 and 11 of Institut Pasteur's patent.

Scope of Claim 11

The appeal court reminded that:

- Institut Pasteur had amended this claim in the examination procedure, to distinguish it from the NIH prior patent; the appeal court stressed that Institut Pasteur cannot argue that this prior art would be irrelevant when it previously argued the contrary, because such turnaround would damage the legal security of third parties;
- the article by Arya, Gallo et al. would anticipate claim 11, if said claim was construed broadly.

The appeal court thus decided that the purified DNA of claim 11 differs from that isolated in prior art documents by its size of approximately 9.1–9.2 kb and its correspondence with the cDNA contained in the deposited clone λ-J19, and thus that this claim must be construed as containing such limitations.

Scope of Claim 8

It then decided that claim 8 could only be construed so as to cover a method for the in vitro detection of HIV using the probes of claim 7, namely a probe consisting of the cloned DNA fragments of claims 1–6 characterized by their restriction sites, their position on the viral genome and their correspondence to the retroviral genome of LAV contained in the deposited clone. The appeal court based such construction on:

- the language of claim 8 and the patent description which does not relate to a general means consisting of hybridizing DNA probes with viral RNA, but which relates to the use of specific probes consisting of given DNA fragments;
- the prior art which already disclosed a general method for the detection of HIV consisting of hybridizing DNA probes with viral RNA.

Reference to the wording of the claim and to the patent description is a correct application of Art. 69 EPC. This first finding provided sufficient grounds for the court's decision. But the appeal court clearly wanted to emphasize the difficult position in which the plaintiff found itself, namely that a broad construction of its patent would entail its invalidity in view of the prior art.

Non-Infringement of Claim 8

The appeal court dismissed Institut Pasteur's claim for infringement of claim 8 on the ground that the plaintiff did not demonstrate that the probes used in the accused kits would, in fact, contain the DNA fragments of claims 1–6 of its patent. But the court added that the accused kit did not even reproduce the other characteristics of claim 8:

- the Chiron probes are synthetic, and even chimeric for some of them, thus not cloned;
- the amplification promoter contains a fragment, which is not in the DNA contained in λ-J19.

The appeal court also mentioned that Institut Pasteur cannot rely on the doctrine of equivalents because claim 8 does not cover a new general means for the

detection of the LAV, but only a specific method. This finding is consistent with well-established case law regarding contributory infringement.

Non-Infringement of Claim 11

The appeal court relied on two findings to dismiss Institut Pasteur's argument that the Chiron companies had indirectly infringed claim 11 of the patent. First, it noted that contributory infringement only applies when the means supplied relate to an essential element of the invention, i.e. when the supplied means contribute to the result of the invention. In this respect, the court seemed to follow the defendant's argument that the means supplied did not relate to an element of the claim because it did not relate to an integer of claim 11; it noted that claim 11 does not cover a method comprising a purification step, but a product, namely purified RNA. Secondly, the court held that the means supplied (i.e. the isolation step of the Chiron kit) are not suitable to implement the invention because Institut Pasteur did not prove that the use of the accused kit would permit the isolation of the specific RNA of claim 11, as construed.

Conclusion

Despite the complex technology at stake, the Paris Court of Appeal, like the Paris District Court, issued a well-reasoned and easy to understand decision. The appeal court relied on ordinary rules of patent construction (Art. 69 European Convention) and made it clear that these apply equally to pioneer inventions. The court also relied on the ordinary rules governing the assessment of the scope of the patent in view of the prior art. On this issue however, the appeal court explicitly reminded the changes made by the patentee during the examination and opposition procedures, not so much to accept a prosecution history estoppel but to protect the legal security of third parties.

This decision, the first ever issued by a French court of appeal addressing infringement of a patent on molecular biology, shows that general concepts of patent law, when properly applied, provide appropriate tools for deciding complex cases involving new technology.

*Pierre Véron and Thomas Bouvet**

* The authors represented Chiron in this matter.

GERMANY

Patent Act, Sec. 8; International Patent Convention Act, Art. II, Sec. 5(1), first sentence – "Antiglare Curtain" (Blendschutzbehang)

a) If the application for a patent for an invention is in part due to the contribution of a person other than the applicant, there may also be a claim to the grant of joint entitlement even if the application is divisible (distinguishing decision of the Federal Supreme Court dated 6 March 1979, Case No. X ZR 60/77, 1979 GRUR 692 – *Spinnturbine I*)

b) Joint entitlement can only be granted to the patent application as a whole and not to parts of the application such as individual patent claims

Decision of the Federal Supreme Court (Bundesgerichtshof)
12 March 2009– Case No. Xa ZR 86/06

Facts:

1 The plaintiff operates *inter alia* the F. Institute in F. (hereinafter: the Institute). In summer 2001, the defendant who was then the managing director of C. GmbH approached the Institute to discuss the