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FRANCE

European Patent Convention. Art. 69 - "In vitro detection of HIV infection"

Patent claim for a method for the in vitro detection of viral infection due to LAV (HIV) covered only a method using the probes mentioned in the patent claim, namely probes containing DNA sequences characterized by their restriction sites and the fact that they correspond to a deposited clone; the claim thus did 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 was dismissed because the plaintiff did not show evidence of the alleged infringement.

The action for contributory infringement of a patent claim covering purified RNA was dismissed because the diagnostic kits containing a purification step, supplied by the defendant, did not relate to an essential element of the patent claim.

Decision of the Paris District Court (Tribunal de Grande Instance)
February 7, 2007, case No. 05/11023

Facts:

The French research organization, Institut Pasteur, filed European patent No. 0 178 978 on September 17, 1985, under British priority of September 19, 1984 for "cloned DNA sequences, hybridisable with genomic RNA of

lymphadenompathy-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 August 19, 1985 under the priority of the US patent application of August 22, 1984, published on March 5, 1986, and thus relevant for novelty considerations only.

Chiron Blood Testing SAS and Chiron Healthcare Ireland Ltd 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 by summons served on 25 July, 2005, just three months before the expiry of its patent, and requested payment of an account on damages of €8 000 000.

Claims 1–6 of patent No. 0 178 978 relate to cloned DNA which contains a DNA corresponding to the HIV retroviral genome contained in a deposited clone and characterized by its size, or to cloned DNA fragments of the same deposited DNA, characterized by their size and restriction sites.

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)."

Arguments of the parties

The plaintiff, Institut Pasteur, alleged that claim 8 of its patent 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 marketing of Chiron's detection kit infringed claim 8 of its patent, either literally or by way of equivalence.

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 supply ing the means relating to an essential element of that claim.

The defendants, 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 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.

Chiron requested the Court to dismiss Institut Pasteur's action for infringement of claim 8 on the ground that the plain tiff did not demonstrate that the detec tion kit in question would use the probe of claim 7 consisting of 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 essential element of this claim.

Findings:

The Court reviewed:

- the scope of claims 8 and 11 of EP No. 0 178 978; and
- the alleged infringement of those claims.

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

Scope of claim 8

The Court began by quoting Art. 69 EPC. 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 cloned DNA fragments of claims 1–6 defined by their restriction sites and the fact that they correspond to the retroviral genome of LAV contained in the deposited clone.

The 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 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.

The reference to the wording of the claim and to the patent description is, in our view, a correct application of Art. 69 EPC.

This first finding provided sufficient grounds for the Court's decision.

But the 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.

Scope of claim 11

The reasoning followed by the Court in relation to claim 11 was similar.

The Court decided that claim 11 should be construed so as to cover only the claimed purified RNA characterized by its size and the fact that it corresponds to the complementary cDNA contained in the deposited clone. The Court based such construction on the fact that the purified RNA of the LAV virus was known from the prior art.

Although prior art must not be taken into consideration in claim construction, the Court was correct in deciding that the scope of a claim cannot extend beyond the literal wording of that claim when a broader scope would entail the nullity of the claim.

Non-infringement of claim 8

The 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 kits in question would, in fact, contain the DNA fragments of claims 1–6 of its patent.

The Court noted that Institut Pasteur had not challenged Chiron's argument that their probes are different from those described in the patent.

In this respect, the Court also noted Chiron's argument that the detection kits contained 3 oligonucleotides likely to be considered as probes (capture oligonucleotides, amplification primers and labelled probes) and pointed out that Institut Pasteur did not mention which of those oligonucleotides would be infring-

ging, nor whether all or any of those oligonucleotides would reproduce the characteristics of claim 8 as it has been construed.

Although the Court could have ended its judgment at this stage, it went on to add that Chiron had demonstrated that their probes differed from the patented ones.

Non-infringement of claim 11

The Court relied on two findings to dismiss Institut Pasteur's argument that the Chiron companies had indirectly infringed claim 11 of the patent.

First, the Court of Paris noted that contributory infringement only applies when the means supplied relate to an essential element of the invention i.e. when it is one of the claimed characteristics.

It thus dismissed the plaintiff's action on the ground that claim 11 does not cover a process comprising a purification step, but instead a product, namely purified RNA.

The Court held that the kit for capturing viral RNA is not an essential element of claim 11.

Secondly, the Court held that Institut Pasteur had not proven that the RNA captured by the device would be RNA covered by claim 11 and that Institut Pasteur had not rebutted Chiron's submission that the isolated RNA would have a much longer size than that claimed.

Comment:

Despite the complex technology at stake, the Court issued a well reasoned and comprehensible decision.

The Court found at least two grounds on which to base its rejection of each of the plaintiff's arguments.

And in doing so, the Court relied on ordinary rules of patent construction (Art. 69 European Convention) and on the ordinary rules governing the assessment of the scope of the patent in view of the prior art. It recalled that the plaintiff has the burden of proving an alleged infringement.

This decision, the first ever issued by a French Court 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.

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* The authors represented Chiron in this matter