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Institut Pasteur v. Chiron: French patent law not hybridizable with the US “file wrapper estoppel” theory

Pierre Véron (Véron & Associés) · Wednesday, January 12th, 2011

Institut Pasteur is the holder of European patent No. 0 178 978, which relates to “*Cloned DNA sequences, hybridizable with genomic RNA of lymphadenopathy-associated virus (LAV)*”. Institut Pasteur lodged an action against two Chiron companies (hereinafter referred to as Chiron) criticising them for marketing HIV detection kits which allegedly infringed upon claims 8 and 11 of this patent.

The *Tribunal de Grande Instance* of Paris in a 7 February 2007 decision and then the *Cour d’Appel* of Paris in a 4 March 2009 decision dismissed Institut Pasteur’s claims for infringement considering that Chiron’s detection kits fell outside the patent’s protection scope and that their sale did not constitute an infringement.

Institut Pasteur then lodged an appeal against the 4 March 2009 decision of the *Cour d’Appel* of Paris.

The criticisms made by Institut Pasteur in the various branches of its five arguments against the decision of the *Cour d’Appel* of Paris are organised into three points:

– the scope granted by the *Cour d’Appel* of Paris to the claims 8 and 11 which had been amended during the examination and opposition procedure before the EPO (**I**);

– the contributory infringement of claim 11 (**II**);

– the infringement by equivalence of claim 8 (**III**).

On all these points, the Institut Pasteur’s arguments have been dismissed by the French *Cour de Cassation* in a 23 November 2010 decision.

I) Scope of claims 8 and 11

As for the scope of claims 8 and 11 asserted by Institut Pasteur against Chiron, the former, in its first argument, criticised the appeal decision on the basis of Article 69 of the 5 October 1973 Munich Convention and of Article 1 of the Protocol on its interpretation:

– for having taken into account the amendments made to the patent’s claims during the granting procedure of the European patent before the EPO and for not having specified the exact meaning of

those amendments;

– for having confined itself to a literal reading of those amended claims and for having refused to interpret them in the specific light of the description and drawings accompanying the patent on the ground that their wording was non-ambiguous.

The *Cour de Cassation* dismisses this first argument of Institut Pasteur.

Even if the *Cour d'Appel* has noted that the claims had been amended, reduced in number and scope, during the granting procedure of the European patent, it has nevertheless determined the scope of the claims on the basis of their final wording.

This response of the French *Cour de Cassation* is significant as it confirms that the US "file wrapper estoppel" theory is too general to be accepted as such in French patent law; if that theory consists in taking into account the statements made by the applicant during the granting or opposition procedure, Article 69 EPC authorise only claims, description and drawing to be taken into account.

However, to take into account the amendments made during the granting or opposition procedure before the EPO should not be contrary to Article 69 EPC as it is a means to determine with full knowledge the scope of the claims in their final wording. That is the reason why the *Cour d'Appel* did not base its decision on the granting procedure to appraise the scope of the claims but only pointed out that amendments had been made to those claims and appraised the claims in their final wording.

Furthermore, the *Cour d'Appel* had no obligation to provide explanations on the amendments made during the granting procedure. And the *Cour d'Appel* did not content itself with a literal reading of the claims but clearly gave specific grounds for the appraisal of the scope granted to those claims.

In its second argument, relating to claim 11, Institut Pasteur criticised the appeal decision:

– for not having ascertained, in the specific light of the description and drawings, whether this claim should not be granted a broader scope;

– for having retained that the NIH's patent did anticipate Institut Pasteur's patent, whereas to form part of the state of the art and to be deprived of novelty, the invention should be disclosed in a single unquestioned prior art reference;

– furthermore, for not having explained the scope of this allegedly prior art reference (the NIH's patent) and for having considered that this prior art reference suggested that the pX gene has no importance whereas the discovery that the pX gene does not belong to the HIV virus was made only after the patent filing date.

The French *Cour de Cassation* notes that Institut Pasteur, in its pleading, did not make reference to the description or the drawings of patent No. 0 178 978 to define the scope that had to be conferred to claim 11 so that this argument was new and both factual and legal.

The *Cour de Cassation* also dismissed this argument by retaining that the *Cour d'Appel* sufficiently justified the limited scope granted to claim 11 relying on an article published by Arya Gallo on 31 August 1984, *i.e.* before the patent's priority date.

In its third argument, relating to claim 8, Institut Pasteur criticised the appeal decision for being made on contradicting grounds by considering, to justify the limited scope attributed to claim 8 (a DNA/RNA hybridization method for detecting HIV by the use of the probes defined in claim 7 and consequently in claims 1 to 6), that Institut Pasteur, during the examination and opposition procedures, had to amend this claim or the probe claim to which it referred in order to distinguish them from the fragment claims and thus be granted a larger protection, and had to state afterwards that the article published by the NIH's researchers, prior to the patent's priority date, already taught the detection of an infection due to HIV by the use of labelled probes, so that claim 8 could not relate to all diagnostic methods. Furthermore, Institut Pasteur also criticised the appeal decision for having limited the scope of claim 8 without checking whether the probes used in the Chiron's kits did not constitute simple variants or equivalents.

The *Cour de Cassation* also dismisses this argument.

The *Cour d'Appel* did not contradict itself. In order to set aside Institut Pasteur's arguments according to which the process covered by claim 8 allegedly covers any diagnostic method regardless of the type of probe used, the *Cour d'Appel* pointed out firstly that this claim as amended requires using the probe the subject-matter of claim 7, dependent on claims 1 to 6 protecting cloned DNA fragments of HIV, and secondly that the Arya Gallo article published before the patent's priority date already taught the detection of an HIV infection by using labelled probes.

Furthermore, the *Cour de Cassation* underlines that, in the present case, the appraisal of the claim's scope and not the appraisal of the infringement of the claim was at issue. The appraisal of the claim's scope constitutes a distinct examination from that relating to the appraisal of the infringement of a claim so that the *Cour d'Appel* has legally justified its decision by considering that claim 8 did not cover all diagnostic methods (but solely a method using the probes the subject-matter of claim 7), without having any obligation to analyse the probes used in the allegedly infringing Chiron's kits.

II) Contributory infringement of claim 11

Concerning the contributory infringement of claim 11, Institut Pasteur criticised the appeal decision for not having ascertained whether the allegedly infringing detection kit contained in the whole product covered by claim 11.

The *Cour de Cassation* also dismissed this fourth argument. The *Cour d'Appel* held on its own grounds and on adopted grounds that the essential element of claim 11 was the isolation of an RNA fragment corresponding to the complementary DNA contained in ?-J19 and that the allegedly infringing Chiron's kit did not permit one to isolate the claimed RNA fragment so that the accused detection kit was not an essential element of claim 11.

III) Infringement by equivalence of claim 8

About the infringement by equivalence of claim 8, Institut Pasteur reminded that this type of infringement presupposes that the patented means does not fulfil a known function and criticised the appeal decision for not having verified whether the claimed specific means (hybridization of the viral RNA with a probe composed of the claimed DNA fragment corresponding to the genome contained in clone ?-J19) did not fulfill a known function.

The *Cour de Cassation* dismisses this fifth and last argument. The *Cour d'Appel* held that the use of the DNA/RNA hybridization method for detecting HIV was already known (prior art) at the date of the claimed priority so that claim 8 could only cover the specific means of hybridization of viral RNA with a probe composed of the claimed DNA fragment corresponding to the genome contained in clone ?-J19.

The specific means of claim 8 has necessarily a known function since it was only a specific application of the general means of DNA/RNA hybridization which had a known function (detection of HIV).

Original French decision.
English translation.

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This entry was posted on Wednesday, January 12th, 2011 at 3:08 pm and is filed under (Indirect) infringement, G 1/93, OJ 1994, 541) *The 'gold standard'* of the European Patent Office's Board of Appeal is that *any amendment can only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the documents as filed (G 3/89, OJ 1993,117; G 11/91, OJ 1993, 125).*">Amendments, Biologics, EPC, literally fulfil all features of the claim. The purpose of the doctrine is to prevent an infringer from stealing the benefit of an invention by changing minor or insubstantial details while retaining the same functionality. Internationally, the criteria for determining equivalents vary. For example, German courts apply a three-step test known as Schneidmesser's questions. In the UK, the equivalence doctrine was most recently discussed in Eli Lilly v Actavis UK in July 2017. In the US, the function-way-result test is used.">Equivalents, France, Scope of protection
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