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Doctrine of Equivalents and File Wrapper Estoppel in France

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Institut Pasteur is the holder of European patent No. 0 178 978 entitled "*Cloned DNA sequences, hybridizable with genomic RNA of "lymphadenopathy-associated virus (LAV)""*, granted on 6 February 1991. The "*lymphadenopathy-associated virus (LAV)*" is nothing else than the human immunodeficiency virus (HIV) causing acquired immune deficiency syndrome (AIDS) in man.

Bayer Diagnostics, now Siemens Healthcare Diagnostics (hereinafter referred to as "Siemens"), markets since 2003 in France, kits under the name *Versant HIV-1 RNA 3.0 Assay (bDNA)* for the quantitative diagnosis of HIV.

Considering that these detection kits implemented the features of its invention, Institut Pasteur sued Siemens for infringement of claims 5, 7, 8 and 11 of the European patent.

In its claims 5, 7, 8 and 11, the patent of Institut Pasteur claims :

– a method for detection of HIV (claim 8) by contacting a biological sample, originating from a patient and containing RNA, with DNA probes of claim 7 which consists of cloned DNA fragments (this DNA being obtained by cloning of ?J19) characterised by their restriction sites, their size and their location on the HIV genome (claims 1 to 6, claim 5 corresponding to a cloned DNA fragment whose sequence corresponds to the part of the DNA of ?J19, which extends from approximately Kpn I (3500) to approximately Bgl II (6500) thereof);

– a RNA of HIV characterised by its size and ability to hybridize with the complementary DNA contained in ?J19 (claim 11).

The *Tribunal de Grande Instance* of Paris in its 28 May 2010 decision dismisses Institut Pasteur's claim.

Institut Pasteur sought first to attribute to its patent the broadest scope as possible so that the detection kits in litigation would infringe it. Against that Siemens argued that Institut Pasteur was attributing to its patent the scope of previous claims that it was obliged to renounce during the grant and opposition proceedings before the European Patent Office.

First, Institut Pasteur hold that claim 8 protects a new general means and so any detection method regardless of the used probes.

However, Siemens hold that the method taught by claim 8 only covers the use of the cloned DNA

fragments such as defined in claims 1 to 6, i.e. cloned DNA fragments precisely characterised by their restriction sites, their size and location on the genome HIV.

Secondly, Institut Pasteur also hold that claim 11 covers the all RNA of the HIV.

Siemens answered that claim 11 covers only a specific RNA fragment identified by its size, the restriction sites found at its ends and by its ability to hybridize with the complementary DNA contained in ?J19. So, as a main request, Siemens hold that the court should decide on the scope of the Institut Pasteur's patent and, in the alternative, on its validity if the court gives a broad scope to the Institut Pasteur's patent.

The court, in its 28 May 2010 decision, first underlines that the determination of the extent of the protection conferred by a European patent shall be done exclusively according to the provisions of Article 69 EPC and of the Protocol on the Interpretation of Article 69 EPC, i.e. on the basis of the claims, the description and drawings, so that the US "*file wrapper estoppel*" theory (also known as "*prosecution history estoppel*" or "*file history estoppel*" ; wether there is in Europe such a theory, see M. Franzosi, "*Prosecution History Estoppel in Europe*", Italian Intellectual Property, July 2003, No. 2 in English; Revue du droit de la propriété intellectuelle, August 2004, No. 162, p. 35 s. in French), which consists in also taking into account the statements made by the applicant during the grant or opposition proceedings, cannot be applied.

The court is of the opinion that the US "*file wrapper estoppel*" theory is too general to be received as such in French patent law. If that theory consists in taking into account the statements made by the applicant during the grant or opposition proceedings, Article 69 EPC authorize to take into account only the claims, description and drawings.

The court adds that this rejection of the US "*file wrapper estoppel*" theory however exclude in no way the possibility or even the duty – failing which legal certainty for third parties would be violated – for the court of referring to the wording of the claims as initially filed and to the amendments made during the grant or opposition proceedings before the European Patent Office, in order to determine the extent of the protection conferred by the European patent (same opinion, *Tribunal de Grande Instance* of Paris, 3rd ch., 1st sect., 26 April 2000, Docket No. 96/20939, *Garden Claw International v. Leborgne*; *Cour d'Appel* of Paris, 4th ch., sect. B, 5 July 2002, Docket No. 2001/21923, *La Johnson Française v Sara Lee*; *Tribunal de Grande Instance* of Paris, 3rd ch., 1st sec., 26 January 2005, Docket No. 02/10303, *Lely v. Kverneland*).

This solution, rejecting the "*file wrapper estoppel*" theory but admitting the taking into account of amendments made during the grant or opposition proceedings before the European Patent Office in order to determine with full knowledge the extent of the protection, is a very good illustration of French law which does not know a general estoppel theory but its case law adopts solutions which may be in line with such a theory (see P. Véron, "*Doctrine of Equivalents: France v. The Rest of the World*", Patent World, November 2001, p. 3; M. Franzosi, cited above; E. Gutmann, "*De l'effet possible des modifications apportées aux revendications d'un brevet européen avant sa délivrance sur l'étendue de la protection finalement conférée à l'invention*", Propriétés intellectuelles 2002, No. 5, p. 69 et seq.; see also *Cour d'Appel* of Paris, 4th ch. B, 14 May 1999, *Bobst v. United Container Machinery Group*, where the court did not decide on the basis of the statements made by the applicant during the grant proceedings of the US and European patents but mentioned them "*as a matter of interest*").

The court has therefore given to the patent a limited scope which corresponds to the wording of the amended claims and not the broad scope claimed by Institut Pasteur. Consequently, the extent of the patent being so cut down to size, the court had no reason to examine the claim for invalidity of the Institut Pasteur's patent subsidiarily lodged by Siemens on the assumption that a broad scope would be given to the patent.

As for the alleged infringement committed by Siemens, the court takes into account the extent of the claims 5 and 6 and decides that there was no direct infringement.

The court underlines that the probes of the alleged infringing detection kits are not composed of cloned DNA and, if it is assumed that they are placed end to end, they are not located on the fragment of claims 5 and 6. Claims 5 and 6 are independent from each other and cannot be combined to appraise the infringement. Consequently, claims 7 and 8 are also not infringed by the detection kits in litigation since they depend directly on claims 5 and 6.

The court also decides that there was no infringement by equivalence. The court's conclusion must certainly be approved. However, the wording of its decision is not happy. The court states :

> "*It follows that the patented means, that is the use of probes composed of DNA fragments, is only new in its form, as the fulfilled function of hybridization with the viral RNA for detecting the disease is known;*
>
> The infringement by equivalence, which, in the present case, cannot result from the identity of functions, can be constituted only if the very form of the patented means is implemented in an equivalent form and in what characterizes its patentability, namely, in the present case, probes composed of cloned DNA fragments defined by their restriction sites and corresponding to the retroviral genome contained in clone ?-J19;
>
> The accused capture probes and target probes, which each comprise, as stated, approximately 20 to 30 synthetic nucleotides and which bind to the sequence of bases of the HIV-1 virus comprised between 1555 and 4568 cannot be considered the equivalent of the probes constituted by the cloned DNA fragments according to patent claims 1 to 6;
>
> Nor can the infringement by equivalence be held"

It creates confusion by suggesting that there may be two kinds of infringement by equivalence: equivalence of function when the function of the patented means is new, equivalence of form when the function of the patented means is already known but the form of the alleged infringing means is very close to the form of the patented means. It must be reminded that the latter case is nothing else than a literal infringement, which can be achieved despite minor variants, or when the alleged infringing means is only a variant of execution. Such is the doctrine of equivalents commonly applied by French Courts (*Cour d'Appel* of Paris, 1 December 1988, Annales de la Propriété Industrielle, 1988, 292 ; *Cour de Cassation, Chambre Commerciale*, 18 June 1996, PIBD 1996, No. 619, III, 511 ; *Cour d'Appel* of Paris, 30 October 1996, PIBD 1997, No. 626, III, 78 ; *Cour d'Appel* of Paris, 4th ch., sect. A, 25 May 2005, PIBD 2005, No. 814, III, 485 ; *Tribunal de Grande Instance* of Paris, 3rd ch., 1st sect., 6 July 2005, PIBD 2005, No. 817, III, 612; *Cour*

d'Appel of Paris, 4th ch., sect. B, 22 December 2006, PIBD 2007, No. 847, III, 48 ; *Cour de Cassation Chambre Commerciale*, 20 November 2007, PIBD 2008, No. 866, III, 29 "*infringement by equivalent means implies that the patented method does not have a known function*" ; *Cour d'Appel* of Paris, 13 February 2009, PIBD 2009, No. 894, III, 945 ; see P. Véron, cited above, p. 2).

Lastly, as for the infringement of claim 11, Institut Pasteur hold that the alleged infringing detection kit was an essential element for putting this claim into effect since it permits to isolate the viral RNA present in the infectious viral particles found in the patient. Siemens would have then committed a contributory infringement (Art. L. 613-4 of the French Intellectual Property Code) of claim 11.

Because of the limited scope given to claim 11 (an RNA strand precisely defined by its size, on the one hand, and by its ability to hybridize with the complementary DNA contained in ?-J19), the court decides that Institut Pasteur has in no way shown or even alleged that the RNA isolated by the Siemens' kits would allow the accurate isolation of the RNA fragment of claim 11. Therefore, there was no contributory infringement of claim 11.

Original French decision.
English translation.

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This entry was posted on Friday, July 30th, 2010 at 3:36 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, Extent of Protection, France
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