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Datasheet for the decision of 17 August 2006

Case Number:	T 0759/03 - 3.3.04
Application Number:	92912386.7
Publication Number:	0602046
IPC:	C07K 7/06

Language of the proceedings: EN

Title of invention:

Detection of feline immunodeficiency viruses

Patentees

ST. VINCENT'S INSTITUTE OF MEDICAL RESEARCH LIMITED, et al

Opponent:

IDEXX Laboratories, Inc.

Headword:

FIV/ST. VINCENT'S INSTITUTE, et al

Relevant legal provisions:

EPC Art. 54, 56, 83, 84, 123

Keyword:

"New main request - added subject-matter - (no), novelty, inventive step, sufficiency, clarity - (yes)"

Decisions cited:

T 0019/90, T 0750/94, T 0333/97, T 1045/98, T 0190/99

Catchword:

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Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 0759/03 - 3.3.04

D E C I S I O N of the Technical Board of Appeal 3.3.04 of 17 August 2006

Appellant:	IDEXX Laboratories, Inc.	
(Opponent)	One IDEXX Drive	
	WESTBROOK, Maine 04092	(US)

Representative:

Helbig, Christian Frohwitter Patent- und Rechtsanwälte Possartstrasse 20 D-81679 München (DE)

Respondents: (Patent Proprietors)

ST. VINCENT'S INSTITUTE OF MEDICAL RESEARCH LIMITED et al 41 Victoria Parade Fitzroy, VIC 3065 (AU)

Representative:

Taormino, Joseph Hoffmann Eitle Postfach 81 04 20 D-81904 München (DE)

Decision under appeal: Interlocutory decision of the Opposition Division of the European Patent Office posted 16 May 2003 concerning maintenance of the European patent No. 0602046 in amended form.

Composition of the Board:

Chair:	U.	Kinkeldey
Members:	м.	Wieser
	R.	Moufang

Summary of Facts and Submissions

- I. The appeal was lodged by the Opponent (Appellant) against the interlocutory decision of the Opposition Division, according to which the European patent No. 0 602 046 could be maintained in amended form pursuant to Article 102(3) EPC.
- II. The patent had been opposed under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), under Article 100(b) EPC on the ground of lack of sufficient disclosure (Article 83 EPC) and under Article 100(c) EPC on the ground of added subject-matter (Article 123(2) EPC).
- III. The Opposition Division had decided that the subjectmatter of the claims of the main request before them, namely the claims as granted, were not novel and did not meet the requirements of Article 54 EPC. However, they decided that claims 1 to 16 for all designated Contracting States except ES and claims 1 to 15 for ES of the first auxiliary request met all requirements of the EPC.
- IV. The Board expressed its preliminary opinion in a communication dated 13 February 2006.

Oral proceedings were held on 17 August 2006 at the end of which the Chair announced the decision of the Board.

V. The Appellant requested that the decision under appeal be set aside and that the patent be revoked. The Patent Proprietors (Respondents) requested that the decision under appeal be set aside and that the patent be maintained in amended version on the basis of claims 1 to 14 for all designated Contracting States except ES and claims 1 to 13 for ES (new main request filed at the oral proceedings).

VI. Claim 1 of the new main request for all designated Contracting States except ES read:

> "A peptide consisting of an immunodominant region of an envelope protein of a feline immunodeficiency virus, which peptide comprises two cysteine residues, optionally linked to form a disulphide loop; said peptide comprising at least eight consecutive amino acids derived from amino acids 680 to 711 of the env gp 40 protein of feline immunodeficiency virus, having the sequence:

KVEAMEKFLYTAFAMQELGCNQNQFFCKIPLE,

or a peptide comprising analogues or conservative substitutions for the amino acids in said sequence, or in which the sequence is extended by the addition of further amino acids to the N-terminal and/or the C-terminal of said sequence, or in which amino acids are deleted from the N-terminal and/or the C-terminal of said sequence, wherein said peptide retains a conformation such that it is recognized by an antibody directed to said immunodominant region of a feline immunodeficiency virus envelope protein."

Dependent claims 2 to 6 referred to preferred embodiments of the peptide. Claims 7 and 8 related to methods of preparing the peptide. Claim 9, and claim 11 dependent thereon, referred to an immunoassay using the peptide. Claim 10 and dependent claims 12 to 14 related to a test kit comprising the claimed peptide.

VII. Claim 1 for ES referred to a method of preparing a peptide having the characterising features of the peptide of claim 1 as indicated in section (IV) above, by a method selected from the group consisting of recombinant DNA technology and chemical synthesis. According to claim 2 this method was defined as being chemical synthesis. Dependent claims 3 to 7 related to preferred embodiments of the methods of claims 1 and 2. Claims 8, and claim 10 dependent thereon, referred to a method for preparing an immunoassay using the prepared peptide, claim 9, and dependent claims 11 to 13, referred to a method of providing a test kit containing the peptide.

> If not otherwise specified, the present decision when referring to claim 1 means claim 1 for all designated Contracting States except ES.

VIII. The present decision refers to the following documents:

- (1) WO-90/06 510
- (2) Proc. Natl. Acad. Sci. USA, vol.86, 1989, pages 8088 to 8092
- (3) WO-90/13 573
- (7) Mermer B., Poster Presentation alleged to be presented at Cold Spring Harbour Conference, USA,

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21 to 26 May 1991; pages 1, 2 and 4 to 8

- (8) Statement of Brion Mermer, filed by the Appellant on 19 August 1998
- (21) Vet. Immunol. Immunopathology, vol.35, 1992, pages
 133 to 141
- (26) List of Abstracts of Papers presented at the 1991 meeting on RNA Tumor Viruses 21 to 26 May 1991, Cold Spring Harbour, USA
- (28) Affidavit of P. Andersen, dated 25 September 2003
- (32) Affidavit of R. Groat, dated 25 September 2003
- (49) Affidavit of R. Groat, dated 27 April 2005
- IX. The submissions made by the Appellant, as far as relevant to the present decision, may be summarised as follows:

The introduction of the term "consisting" into the claims of the new main request had no basis in the application as filed. The claimed embodiment wherein the two cysteine residues of the disclosed sequence were only optionally linked to form a disulphide bond was also not based on the application as filed, which solely referred to embodiments exhibiting a disulfide loop. Finally, the original application did not contain a basis for the claimed analogues, conservative substitutions, sequence additions or deletions as covered by claim 1.

Moreover, the introduction of the term "consisting" into claim 1 rendered the claim unclear. The scope of the claim included full-length gp40 and gp130 and was therefore not novel over the disclosure in documents (1) to (3) and (7) (Article 54 EPC). With regard to document (7) the Opposition Division was wrong in their decision not to consider it as prior art as the document was available to the public prior to the effective date of the patent in suit. Additional evidence for this was provided in documents (27) and (28).

A skilled person, either starting from the disclosure in document (1) or in document (3), would have arrived at the claimed subject-matter in an obvious way contrary to the requirements of Article 56 EPC. The alleged problem underlying the patent in suit, namely the provision of an immunodominant region of FIV having greater specificity and sensitivity, compared to available assays known in the art, had not convincingly been solved.

The skilled reader did not receive any guidance which changes had to be introduced into the sequence depicted in claim 1 to obtain functional analogues comprised in the scope of the claim. Extensive and undue experimentation would have been necessary to achieve this goal. Therefore the subject-matter of the claims lacked enablement (Article 83 EPC).

X. The submissions made by the Respondent, as far as relevant to the present decision, may be summarised as follows:

> The claims had an exact basis in the application as filed and met the requirements of Article 123(2) EPC. The introduction of the term "consisting" into claim 1 did not render the claim unclear, but reinforced that the claim referred to a peptide fragment and not to full-length gp40 and gp 130. The disclosure in documents (1) to (3) was therefore not novelty destroying (Article 54 EPC).

> The evidence provided by the Appellant did not convincingly show that document (7) was publicly available prior to the effective date of the patent in suit. The high standards required by the case law of the Boards of Appeal in such questions were not met.

> Starting from document (3) as representing the closest state of the art, the problem underlying the patent in suit was the provision of an immunodominant region of env gp40 of FIV having improved specificity and sensitivity. This problem had been convincingly solved by providing the peptide according to claim 1. Neither the disclosure in document (3) nor in any other cited prior art document would have allowed a skilled person to arrive at this subject-matter in an obvious way (Article 56 EPC).

The Appellant, alleging that the analogues comprised in claim 1 were not enabled (Article 83 EPC), had not provided any verifiable facts to demonstrate the validity of this supposition.

Reasons for the decision

Amendments - Articles 123(2) and 123(3) EPC

1. Claim 1 refers to "a peptide consisting of an immunodominant region of an envelope protein of a feline immunodeficiency virus" and is based on page 7, lines 12 to 15, page 8, lines 5 to 12 and claim 3 of the PCT application published as WO 92/22 573.

> According to page 12, lines 16 to 20 of the published application, peptides having the disclosed sequence contain internal disulphide bonds, which may be used in either oxidised or reduced form. According to page 11, lines 4 to 15, peptides of the invention may comprise analogous or conservative substitutions for the amino acids recited in the indicated sequence, provided the conformation recognised by an appropriate antibody is preserved. The sequence disclosed may also be either extended by further amino acids at either terminus, or alternatively modified by deletion of amino acids.

> Present claims 2 to 4 are based on claims 5 to 7 and example 3 of the published application. Claims 5 and 6 are based on page 12, lines 17 to 18. Claims 7 and 8 are based on claims 8 and 9, and claims 9 to 14 on page 10, lines 10 to 25, example 4 and claims 11 and 13 of the published application.

Claims 1 to 13 of the new main request for ES are based on the same original disclosure. These claims have been adapted in order to take into account the reservations made by ES provided for in Article 167(2) EPC.

- 2. Claim 1 of the new main request differs from claim 1 as granted only by the insertion of the term "consisting". Accordingly, the claim has not been amended during opposition proceedings in such a way as to extend the protection conferred.
- 3. Claims 1 to 14 of Respondent's new main request for all designated Contracting States except ES and claims 1 to 13 for ES meet the requirements of Articles 123(2) and 123(3) EPC.

Clarity - Article 84 EPC

4. Article 84 EPC requires that the claims shall define the matter for which protection is sought. They shall be clear and complete and be supported by the description.

> However, Article 84 EPC being an EPC requirement concerning patent applications, has to be taken into account in opposition and opposition/appeal proceedings only in so far as it concerns amendments made by the Patent Proprietor to the claims as granted. As already mentioned in point (2) above, in the present case the only amendment of claim 1 results from the introduction of the term "consisting".

5. The peptide of claim 1 is required to consist of an immunodominant region of an env protein of FIV. The peptide has to comprise two cysteine residues and at least eight consecutive amino acids derived from amino acid sequence 680 to 711 of env gp40 of FIV. Furthermore, the claimed peptide, provided it retains a conformation recognized by an antibody directed to said immunodominant region, may comprise analogous or conservative substitutions, or may be extended or shortened at each terminus.

The description of the patent in suit establishes in various passages that the underlying invention is concerned with an immunodominant peptide in the highly conserved transmembrane portion of the env gp 40 protein of FIV (paragraph bridging pages 6 and 7; page 7, lines 11 to 15; page 20, lines 22 to 27 of the published WO application).

- 6. According to the established case law of the Boards of Appeal, the skilled person when considering a claim should rule out interpretations which are illogical or which do not make technical sense. He should try, with synthetical propensity i.e. building up rather than tearing down, to arrive at an interpretation of the claim which is technically sensible and takes into account the whole disclosure of the patent (Article 69 EPC). The patent must be construed by a mind willing to understand not a mind desirous of misunderstanding (cf decision T 190/99 of 6 March 2001; point (2.4)).
- 7. In the light of the disclosure in the patent in suit as a whole, a mind willing to understand would conclude that claim 1 refers to a peptide consisting of an

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immunodominant region. The peptide is a part of the env gp40 protein of FIV and has the characterizing features indicated in said claim, or may alternatively contain the indicated alterations, provided it retains the desired conformation.

8. The introduction of the term "consisting", being the only amendment of claim 1 when compared with claim 1 as granted, does not add any unclarity to the claim. Accordingly, the Board decides that the amendment made to claim 1 meets the requirements of Article 84 EPC.

Sufficiency of disclosure - Article 83 EPC

9. The patent in suit discloses inter alia a peptide having a defined sequence of 32 amino acid residues, representing positions 680 to 711 of the env gp40 protein of FIV.

> The Appellant argues that claim 1 is not restricted to peptides having this sequence or parts thereof, but additionally refers to functionally equivalent alternatives, comprising analogous or conservative substitutions and extensions or shortenings at each terminus. He argues that a skilled person trying to work the invention and to find out if an embodiment falling within the scope of the claim is part of the invention had to perform extensive experimentation which amounted to undue burden.

10. To support this argument the Appellant provided experimental results (documents (32) and (49)), wherein the specificity and sensitivity of synthetic peptides consisting of amino acid sequences representing

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variations to the sequence depicted in present claim 1 against anti-FIV antibodies were determined. It was shown that several of these synthetic peptides gave inferior results when compared with the specificity and sensitivity of Appellant's anti-FIV immunoassay ("Pet Check Test").

- 11. However, the Appellant acknowledged in the oral proceedings that the anti-FIV immunoassay ("Pet Check Test") used as comparative test in the experiments provided in documents (32) and (49) was not identical with the assay that was available under the same name at the relevant date of the patent in suit. Therefore, the results provided in documents (32) and (49) are not considered in the present case.
- 12. The mere fact that a claim is broad, that means in the present case that it refers to a large number of functionally equivalent alternatives to a given peptide sequence, is not in itself a ground for considering the application as not complying with the requirement for sufficient disclosure under Article 83 EPC. Only if there are serious doubts, substantiated by verifiable facts, may an application be objected to for lack of sufficient disclosure (cf decision T 19/90, OJ EPO 1990, 476; point (3.3)).

As no such verifiable facts have been provided in the present case, the Board decides that the patent in suit discloses the invention according to the claims of the new main request in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Availability of document (7)

- 13. The Appellant alleged that document (7) has been presented at the Cold Spring Harbour Conference in New York, US, on 21 to 26 May 1991, before the priority date of the patent in suit, and argued that its content had therefore to be taken into consideration for the assessment of novelty and inventive step.
- 14. Document (7) consists of seven pages which are numbered in a hand-written manner as pages 1, 2 and 4 to 8. The document does not indicate any date or place of its presentation, nor does it allow to identify its authors or the source of its preparation. While pages 1, 2, 5, 6 and 7 of document (7) are presented in a uniform font which reminds of the format which is normally used for poster presentations at conferences and congresses, pages 4 and 8 are printed in a different font and format.
- 15. The Appellant filed documents (8) and (26) during the opposition procedure and documents (27) and (28) during the appeal procedure to prove his allegation, namely that document (7) was publicly available at the relevant date of the patent in suit.
- 16. Document (8) is a declaration of Brion Mermer, coauthor of document (7). It is stated that the document includes an abstract which was distributed to the attendees at a conference on RNA Tumor Viruses at Cold Spring Harbour Laboratory in Cold Spring Harbour, New York, not later than 26 May 1991. Moreover, it is declared that the document includes a reproduction of

posters which were exhibited at the same conference at least as early as 26 May 1991.

- 17. Document (26) is a list indicating the authors and titles of abstracts and papers presented at the 1991 meeting on RNA Tumor Viruses on 21 to 26 May 1991 in Cold Spring Harbour, New York. Number (256) on page (xxxiv) of this list refers to an abstract of B. Mermer with the title: "Similarities between the transmember [sic] proteins of FIV and HIV."
- 18. Document (27) is a letter from Edward B. Stephens, Professor at the University of California, dated 2 June 1991, to B. Mermer. In the letter Prof. Stephens states that he was impressed by B. Mermer's poster presentation at the Cold Spring Harbour Conference on the monoclonal antibodies directed to the FIV gp40.
- 19. Document (28) is an affidavit by Phil Andersen, a further co-author of document (7). In this affidavit, dated 25 September 2003, Mr. Andersen states that the poster was presented by Brian Mermer at the Cold Spring Harbour Conference and that he, as a participant of the Conference, visited the poster on 24 May 1991 in the Main Conference Hall.

Mr. Andersen's affidavit further contains a description of the alleged content of the poster and, in its annex A2, eight pages of which the poster allegedly consisted. None of the pages is numbered. The first page is an abstract with the title "SIMILARITIES BETWEEN THE TRANSMEMBRANE PROTEINS OF FIV AND HIV", which has no counterpart in document (7). Its font differs from the font of any other page of document (7). 20. According to the established case law of the Boards of Appeal, a strict standard of proof has to be applied in ascertaining the facts relating to the public availability of an alleged prior art document. A finding that a publication forms part of the state of the art for the purpose of Article 54(2) EPC should only be made after subjecting the available evidence to a strict and careful evaluation (cf decision T 750/94, OJ EPO 1998, 32, point 4 of the reasons). The burden of proof lies with the party claiming that the information in question was made available to the public before the relevant date (cf Case Law of the Boards of Appeal of the EPO, 4th Ed. 2001, chapter 1.7.2).

21. On the basis of the written evidence on file, considering in particular documents (8) and (26) to (28), the Board is prepared to assume that, at the Cold Spring Harbour Conference in May 1991, Brion Mermer made a poster presentation relating to monoclonal antibodies directed to transmembrane proteins of FIV. However, the Board does not regard the evidence as sufficient for proving the precise content of this presentation beyond reasonable doubt.

> As already noted above (point 14), the document (7) itself does not contain any indication of the date or place of its presentation, nor does it allow to identify its authors or the source of its preparation. The document uses different fonts and its pages are numbered in a handwritten manner, apparently lacking a page 3. Although it is stated in the affidavit of B. Mermer that document (7) includes an abstract which was distributed at the conference, document (7) as

filed by the Appellant does not appear to contain any abstract at all. These facts raise serious doubts as to whether document (7) is a true and complete copy of the poster as allegedly presented at the Cold Spring Harbour Conference in May 1991.

These doubts are not overcome by the affidavit of P. Andersen. The document attached to the affidavit as annex A2 and alleged to have been presented as the poster is not identical with document (7) since it contains a new first page which is furthermore written in a different font and since its pages are not numbered at all (see above, point 19). In addition the affidavit does not give any explanation how its author was able to recollect the presentation of the pages of annex A2 at a scientific conference which predates the date of the affidavit (September 2003) by more than 12 years. In particular there is no information as to whether and how the document was archived. The affidavit does not go beyond its literal content and as such does not allow the Board to assess the associated or background factors. Since the author of the affidavit was not offered as a witness, neither the Opposition Division nor the Board could establish the relevant facts on the basis of testimony at a hearing according to Article 117(1)(d) EPC (see Guidelines for Examination in the European Patent Office, E-IV, 1.2).

22. Since the Appellant has thus failed to discharge the burden of proof which he bears, the Board is not convinced that document (7) was available to the public before the relevant date of the patent in suit. Thus the Board decides that document (7) does not belong to the state of the art (Article 54(2) EPC) and that it is not considered for the assessment of novelty and inventive step.

Novelty - Article 54 EPC

23. Claim 1 refers to a **peptide** consisting of an immunodominant region of an envelope **protein**.

The Board accepts that the borderline between the two technical terms "peptide" and "protein" may not be precise but in the present case, given the definitions in the patent in suit, the difference between proteins, being complex, high-molecular-mass, organic compounds that consist of amino acids arranged in a linear chain linked by peptide bonds, and peptides, which are short molecules formed from the linking of various α -amino acids, as generally accepted in the art, does apply.

24. Document (1) refers to monoclonal antibodies specific for various FIV proteins selected from the group of p10, p15, p26, p47, p110, gp40 and gp130. The document does neither disclose the sequence of these proteins nor does it refer to a specific immunodominant region thereof.

> Document (2) refers to the nucleotide sequence analysis of FIV. Amongst others, it identifies three viral specific glycoproteins, namely gp140, gp100 and gp36 (transmembrane). The deduced amino acid sequence of the analyzed env gene in figure 3 on page 8090 contains amino acids 680 to 711 of the env gp40 protein as indicated in present claim 1. Document (2) does not refer to an immunodominant region of an env protein.

Document (3) discloses purified peptides comprising an epitope of an antigenic FIV polypeptide and their use in an immunoassay for anti-FIV antibodies (see claims and example 2). The amino acid sequences of three peptides derived from p10, p15 and p26 protein of FIV are disclosed in claim 13.

25. The subject-matter of the claims of Respondent's new main request, in the two different sets of claims for the different designated Contracting States, is not anticipated by the disclosure in these prior art documents or in any other document on file.

The requirements of Article 54 EPC are met.

Inventive step - Article 56 EPC

- 26. In accordance with the problem and solution approach, the Boards of Appeal in their case law have developed certain criteria for identifying the closest prior art providing the best starting point for assessing inventive step. It has been repeatedly pointed out that this should be a prior art document disclosing subjectmatter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications (cf Case Law of the Boards of Appeal of the European Patent Office, 4th Edition 2001, chapter I.D.3.1).
- 27. Claim 1 refers to a peptide consisting of an immunodominant region of the env gp40 protein of FIV. The peptide is used in an immunoassay for detecting

antibodies against FIV (claim 9) and in a test kit for performing this immunoassay (claim 10).

28. Considering the criteria elaborated by the Boards of Appeal, the present Board concludes that document (3) represents the closest state of the art (see point (24) above).

> The problem to be solved in the light of the disclosure in document (3) is the provision of a peptide consisting of an immunodominant region of FIV useful for the detection of FIV having greater specificity and sensitivity, compared to available assays known in the art.

29. The following questions have to be answered by the Board:

(i) Has the above problem been solved by the patent in suit over the entire scope of the claims?

(ii) Do the cited prior art documents contain information that would encourage a skilled person, trying to solve the problem, to modify the disclosure in the closest prior art and to arrive at the claimed subject-matter in an obvious way?

30. With regard to the first question the Appellant argues that not all peptides falling within the scope of claim 1 have greater specificity and sensitivity, compared to available assays known in the art.

However, in the experimental tests carried out by the Appellant in documents (39) and (42) in order to prove

this allegation a reference assay was used ("Pet Check Test") which was not available to the public at the relevant date of the patent in suit (see points (10) to (11) of the present decision). The results of these experiments are therefore not relevant for the present decision.

- 31. Example 3 on page 7 of the patent in suit (pages 13 to 14 of the published application) discloses the results of comparative tests with an assay using a 36 amino acid peptide comprising amino acids 680 to 711 of the env gp40 protein of FIV according to claim 1 (see table 2 on page 13) and a commercially available ELISA based on FIV p26 ("Pet Check Test"). It is shown that the ELISA using a synthetic peptide according to claim 1 showed both, greater sensitivity and greater specificity (see table 2 and page 14, lines 1 to 7).
- 32. Furthermore, in document (46) the Respondent submitted data wherein a synthetic peptide consisting of 32 amino acids, namely amino acids 680 to 711 of the env gp protein of FIV as depicted in claim 1, and a second peptide of 36 amino acids, which additionally contained amino acids 712 to 715 of the env gp40 protein of FIV, which peptide is said to be identical to the one used in example 3 of the patent in suit, where tested in an ELISA assay according to said example 3. It was shown that both peptides have a similar pattern of reactivity with regard to sensitivity and specificity.

As a consequence, the Board is convinced that the posed problem has been solved by the subject-matter of the relevant claims of Respondent's new main request. 33. Document (3) refers in claim 6 to the full-length gp40 protein. It does not contain any information or hint that would enable a skilled person to arrive at the peptide according to present claim 1 in an obvious way.

- 34. The Appellant argues that a skilled person would have turned to document (1), which, on page 13, lines 9 to 13, discloses the isolation of monoclonal antibody 2F11 (deposited under the number: ATCC HB10295), capable of recognizing antigenic sites possessed by the env precursor protein gp130 and the transmembrane protein gp40. In order to solve the posed problem, the skilled person would have used this antibody to determine these antigenic sites and would have arrived at the solution according to claim 1 with a reasonable expectation of success.
- 35. The patent in suit claims the priority date 14 June 1991. The Respondent argues that epitope-mapping at this date, more than fifteen years ago, was a complex and difficult task. He takes the view that Appellant's conclusion that a skilled person who was in possession of the antibody of document (1) and who tried to solve the problem underlying the patent in suit would have arrived at the peptide of claim 1 with a reasonable expectation of success is based on mere allegation and neglects all problems and pitfalls involved.
- 36. The Board agrees that in a quickly developing technical field, like the one being concerned in the present case, a method, which today belongs to the everyday routine job of a skilled person, fifteen years ago might have been uncertain and highly complex.

However, in spite of the understandable uncertainties which always characterise experiments using biologic compounds like proteins and antibodies, it has to be asked whether the skilled person at the relevant date of the patent in suit had a reason to adopt a sceptical attitude or if he/she would have had either some expectations of success or, at worst, no particular expectations of any sort, but only a "try and see" attitude, which - as pointed out in decisions T 333/97 of 5 October 2000; point (13) of the reasons - does not equate with the absence of a reasonable expectation of success (cf. decision T 1045/98 of 22 October 2001; point (17) of the reasons).

37. It cannot be inferred from any of the documents cited, including post published documents, that a skilled person, having adopted the "try and see" attitude described above, would have succeeded in providing a peptide according to claim 1, which consists of an immunodominant region of FIV useful for the detection of FIV having greater specificity and sensitivity, compared to available assays in the art.

> Document (21), published after the claimed priority date, highlights that the sequence variability typical of lentiviral env proteins might complicate the design of immunodiagnostics based on env. Although the authors of document (21) report the identification of immunodominant epitopes in the FIV transmembrane protein they have not observed that the inclusion of these epitopes into a FIV antibody ELISA, namely the "Pet Check Test", improved the sensitivity of the assay. They conclude that, rather than FIV env protein derived epitopes, recombinant FIV gag proteins will provide a

reliable diagnostic product of strong predictive value for the detection of FIV infection in cats (document (21), pages 139 to 140).

38. Therefore, in the light of the disclosure in the cited documents, the Board judges that a skilled person trying to solve the problem underlying the patent in suit and to provide a peptide consisting of an immunodominant region of FIV useful for the detection of FIV having greater specificity and sensitivity, compared to available assays known in the art, would not have arrived at the peptides of claims 1 to 6 in an obvious way.

The same applies to methods for producing the peptides (claims 7 and 8), to immunoassays using the peptides (claims 9 and 11) and to test kits comprising the peptides (claims 10 and 12 to 14).

The subject-matter of claims 1 to 14 of Respondent's new main request for all designated Contracting States except ES involves an inventive step and meets the requirements of Article 56 EPC. The same applies to claims 1 to 13 for ES.

- 1. The decision under appeal is set aside.
- 2. The case is remitted to the department of first instance with the order to maintain the patent in amended form on the basis of the following documents:

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- claims 1 to 14 for all designated Contracting States except ES, filed at the oral proceedings,
- claims 1 to 13 for ES, filed at the oral proceedings,
- pages 3, 7, 8 and 10 of the patent specification,
- page 9 as received on 26 June 2000,
- pages 4 to 6 filed at the oral proceedings,
- figure 1 of the patent specification.

Registrar:

Order

Chair:

P. Cremona

U. Kinkeldey

For these reasons it is decided that: