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D E C I S I O N
of 16 February 2005

Case Number: T 0748/01 - 3.3.04

Application Number: 90124241.2

Publication Number: 0489968

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Language of the proceedings: EN

Title of invention:
Synthetic antigens for the detection of antibodies to hepatitis C virus

Patentee:
Innogenetics N.V.

Opponent:
Chiron Corporation

Headword:
HCV antigen I/INNOGENETICS

Relevant legal provisions:
EPC Art. 56

Keyword:
"Main first to third auxiliary requests - inventive step (no)"
"Final auxiliary request 8 - inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0748/01 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 16 February 2005

Appellant: (Proprietor of the patent)
Innogenetics N.V.
Industriepark Zwijnaarde 7
Box 4
BE-9710 Gent (BE)

Representative:
De Clercq, Ann
De Clercq, Brants & Partners c.v.
Edgard Gevaertdreef 10a
BE-9830 Sint-Martens-Latem (BE)

Respondent: (Opponent)
Chiron Corporation
4560 Horton Street
Emeryville
California 94608-2917 (US)

Representative:
Woods, Geoffrey Corlett
J.A. Kemp & Co.
14 South Square
Gray's Inn
London WC1R 5JJ (GB)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 5 July 2001 revoking European patent No. 0489968 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chair: U. M. Kinkeldey
Members: G. L. Alt
S. C. Perryman

Summary of Facts and Submissions

I. The appeal lies against the decision of the Opposition Division to revoke European patent No. 0 489 968 because the three claim requests before it (all containing amendments compared to the claims as granted) respectively did not comply with the requirements of Articles 123(2), 123(3) or 56 EPC.

II. In a communication sent pursuant to Article 11(1) of the Rules of Procedure of the Boards of Appeal, the Board inter alia gave its provisional view on some of the substantive issues, and granted the request of both parties that the present proceedings be consolidated with those of case no. T 197/02 involving the same parties and relating to a patent granted on a divisional application of the application on which the patent in suit had been granted.

III. Oral proceedings on both appeals took place on 15 and 16 February 2005, attended by both parties.

IV. Of the requests submitted, the following were maintained by the end of the oral proceedings, and the decision thereon was announced by the Board, all earlier requests made having been withdrawn during the course of the oral proceedings:

- main request (submitted labelled auxiliary request 3 at the oral proceedings) in the version for all designated Contracting States except ES, GR, LU and DK;

– first auxiliary request (filed in writing on 14 January 2005 labelled auxiliary request 5), in the version for all designated Contracting States except ES, GR and LU;

– second and third auxiliary requests (filed in writing on 14 January 2005 labelled respectively auxiliary requests 6 and 7), in the versions for all designated Contracting States except ES and GR;

– final auxiliary request (submitted at the oral proceedings labelled auxiliary request 8) in the version for the designated Contracting States AT, BE, CH, DE, DK, FR, GB, IT, LI, LU, NL, SE and in the version for the designated Contracting States ES and GR.

V. Claim 1 of the main request read:

"1. A peptide composition comprising at least one peptide selected from

(a) the group of amino acid sequences consisting of:

(1)
(I) Y-Met-Ser-Thr-Ile-Pro-Lys-Pro-Gln-Arg-Lys-Thr-Lys-Arg-Asn-Thr-Asn-Arg-Arg-Pro-Gln-Z-X.
(20)

(7)
(II) Y-Pro-Gln-Arg-Lys-Thr-Lys-Arg-Asn-Thr-Asn-Arg-Arg-Pro-Gln-Asp-Val-Lys-Phe-Pro-Gly-Z-X.
(26)

(8) (18)
(IIA) Y-Gln-Arg-Lys-Thr-Lys-Arg-Asn-Thr-Asn-Arg-Arg-Z-X.

(13)
(III) Y-Arg-Asn-Thr-Asn-Arg-Arg-Pro-Gln-Asp-Val-Lys-Phe-Pro-Gly-Gly-Gly-Gln-Ile-Val-Gly-Z-X.
(32)

(37)
(IV) Y-Leu-Pro-Arg-Arg-Gly-Pro-Arg-Leu-Gly-Val-Arg-Ala-Thr-Arg-Lys-Thr-Ser-Glu-Arg-Ser-Z-X.
(56)

(49)
(V) Y-Thr-Arg-Lys-Thr-Ser-Glu-Arg-Ser-Gln-Pro-Arg-Gly-Arg-Arg-Gln-Pro-Ile-Pro-Lys-Val-Z-X,
(68)

(61)
(VI) Y-Arg-Arg-Gln-Pro-Ile-Pro-Lys-Val-Arg-Arg-Pro-Glu-Gly-Arg-Thr-Trp-Ala-Gln-Pro-Gly-Z-X,
(80)

(73)
(VII) Y-Gly-Arg-Thr-Trp-Ala-Gln-Pro-Gly-Tyr-Pro-Trp-Pro-Leu-Tyr-Gly-Asn-Glu-Gly-Cys-Gly-Z-X.
(92)

wherein Y is H or a linker arm by which the peptide can be attached to a carrier or solid phase comprising at least one amino acid and as many as 60, most frequently 1 to 10 amino acids, such as cysteine, lysine, tyrosine, glutamic acid or aspartic acid, or chemical

groups such as biotin or thioglycolic acid, Y can be modified by for instance N-terminal acetylation; Z is a bond or a linker arm by which the peptide can be attached to a carrier or solid phase comprising at least one amino acid and as many as 60 amino acids, most frequently 1 to 10 amino acids, such as cysteine, lysine, tyrosine, glutamic acid or aspartic acid, or chemical groups such as biotin or thioglycolic acid;

and X is NH_2, OH or a linkage involving either of these two groups

and provided that when Y or Z-X are (an)amino acid(s), they are different from any naturally occurring HCV flanking regions; or,

(b) the variants of each of the above peptides (I) to (VII), with said variants presenting conservative as well as non-conservative amino acid substitutions accommodating for less than 35 % strain-to-strain variation in HCV sequences with respect to each of the amino acid sequences (I) to (VII) provided that said variant peptides are capable of providing for immunological competition with at least one strain of HCV; or,

(c) fragments of peptides (II), (IIA), (IV) and (V) having at least 6 amino acids of any of the peptide sequences 7-26, 8-18, 37-56, 49-68, as defined above; and said fragments maintaining substantially all of the sensitivity of said peptide sequences from which they are derived, and

provided that said peptides are different from the following list of peptides:

(6) Arg-Arg-Gly-Pro-Arg-Leu-Gly-Val-Arg
(7) Arg-Arg-Gly-Pro-Arg-Leu-Gly-Val-Arg-Ala-Thr-Arg-Lys- Thr-Ser-Glu-Arg-Ser
(8) Ala-Thr-Arg-Lys-Thr-Ser-Glu-Arg-Ser
(9) Gln-Pro-Arg-Gly-Arg-Arg-Gln-Pro-Ile
(11) Met-Ser-Thr-IIe-Pro-Lys-Pro-Gln-Arg-Lys-Thr-Lys-Arg-Asn-Thr-Asn-Arg-Arg-Pro-Gln
(12) Gln-Arg-Lys-Thr-Lys-Arg.
(15) Thr-Gln-Gln-Arg-Lys-Thr-Lys-Arg-Ser
(16) Gln-Gln-Arg-Lys-Thr-Lys-Arg-Ser-Thr
(17) Gln-Arg-Lys-Thr-Lys-Arg-Ser-Thr-Asn
(18) Arg-Lys-Thr-Lys-Arg-Ser-Lys-Arg-Ser-Thr-Asn-Arg
(19) Lys-Thr-Lys-Arg-Ser-Thr-Asn-Arg-Arg
(20) Thr-Lys-Arg-Ser-Thr-Asn-Arg-Arg-Arg
(21) Thr-Lys-Arg-Ser-Thr-Asn-Arg-Arg-Arg-Ser

VI. Claim 1 of the first auxiliary request was identical to claim 1 of the main request except that part (b) of that claim and all disclaimers other than disclaimers (6) to (9) were omitted.

Claim 1 of the second auxiliary request was identical to claim 1 of the main request except that part (c) of the claim and all disclaimers were omitted and at the end of part (b) the following expression was added: "and said variants maintaining substantially all of the sensitivity of said peptide sequences from which they are derived."

Claim 1 of third auxiliary request (auxiliary request 8) was identical to claim 1 of the main request except

that parts (b) and (c) of that claim and all disclaimers were omitted.

VII. Claim 1 of the final auxiliary request was the same for both the two different versions for different Contracting States and read:

"1. A peptide composition characterized in that it contains at least the mixture of peptides

(a) peptides II, III, V, IX and XVIII; or
(12) peptides I, III, V, IX and XVIII,

wherein the peptides are the following:

(1)
(I) Met-Ser-Thr-Ile-Pro-Lys-Pro-Gln-Arg-Lys-Thr-Lys-Arg-Asn-Thr-Asn-Arg-Arg-Pro-Gln
(20)

(7)
(II) Pro-Gln-Arg-Lys-Thr-Lys-Arg-Asn-Thr-Asn-Arg-Arg-Pro-Gln-Asp-VaI-Lys-Phe-Pro-Gly
(26)

(13)
(III) Arg-Asn-Thr-Asn-Arg-Arg-Pro-Gln-Asp-Val-Lys-Phe-Pro-Gly-Gly-Gly-Gln-Ile-Val-Gly
(32)

(49)
(V) Thr-Arg-Lys-Thr-Ser-Glu-Arg-Ser-Gln-Pro-Arg-Gly-Arg-Arg-Gln-Pro-Ile-Pro-Lys-Val
(68)

(1694)
(IX) Ile-Ile-Pro-Asp-Arg-GIu-Val-Leu-Tyr-Arg-Glu-Phe-Asp-Glu-Met-Glu-Glu-Cys-Ser-Gln
(1713)

(2299)
(XVIII) Glu-Thr-Trp-Lys-Lys-Pro-Asp-Tyr-Glu-Pro-Pro-Val-Val-His-Gly-Cys-Pro-Leu-Pro-Pro
(2318)

VIII. The following documents are mentioned in this decision:

D2: EP-A-0 388 232

D16: Japanese Journal of Experimental Medicine, vol. 60, 1990, pages 223-233, Okamoto, H. et al.

Comparative tests filed with the submissions dated 6 May 1994 (during examination proceedings), 20 March 1998 and 6 October 1999 (both during opposition proceedings).

IX. The appellant's arguments in writing and during the oral proceedings, insofar as they are relevant to the present decision, may be summarized as follows:

Main request

– Document D2 should be treated as the closest prior art because it related to HCV polypeptides and suggested their use in diagnostic assays.

- The comparative experiments filed during examination and opposition proceedings showed that the peptides had unexpectedly good immunogenic properties.

- The respondent's criticism on the reliability of these data was not justified.

- Document D2 disclosed on page 32 a table with 17 clones encoding HCV polypeptide which were said in document D2 to have "proven reactivity with sera from NANBH patients". However, one of these, namely clone 33c, covered a region in which it was impossible to find diagnostically significant peptides and this indicated that the information on the antigenicity of the peptides in document D2 could not be relied on to achieve success.

- A skilled person would not necessarily have focussed on clones CA279a or CA290a encompassing sequences of the claimed peptides, but could have chosen any of the other 15 from the table.

- Whereas document D2 disclosed on pages 15 and 16 a list of fragments of the clones of the table on page 32, due to the absence of immunological reactivity data a person skilled in the art would not have considered the list as having any technical value, and therefore would not have investigated the fragments suggested.

- Even if the skilled person had concentrated on these clones, fragmented them and carried out an antigenicity screening, this would not give any

definitive result. Only a real diagnostic test could elucidate the immunogenic properties of the peptides and there still remained the possibility that diagnostically useful peptides might not be found at all. Therefore, the skilled person would have had no reasonable expectation that any of the shorter peptides would be diagnostically useful.

– The "long" peptides of the table on page 32 are said in document D2 to have "proven reactivity with sera from NANBH patients". Therefore, a person skilled in the art would have been tempted to use those in diagnostic assays, but not any others.

– The tendency to use "long" peptides was corroborated by document D16 stating that the authentic core protein of HCV would have to be evaluated for use as an antigen probe in ELISA.

– Consequently, the peptides referred to in claim 1 could not be derived in an obvious manner from the prior art.

First, second and third auxiliary requests

First auxiliary request

– By the omission of part (b) of claim 1 of the main request, the scope of the claim was restricted so that it no longer covered variants and it became even less likely than for the main request that someone starting from document D2 would arrive at something falling under claim 1.

Second auxiliary request

– By the omission of part (c) of claim 1 of the main request, and the further restriction of part (b), it became even less likely than for the main request that someone starting from document D2 would arrive at something falling under claim 1.

Third auxiliary request

– By restriction of claim 1 solely to what was part (a) of claim 1 of the main request, there was no likelihood that someone starting from document D2 would arrive at something falling under claim 1.

Final auxiliary request (auxiliary request 8)

– Document D2 was the closest prior art document.

– The problem to be solved was to provide an optimized diagnostically useful tool reacting with a larger variety of sera from different patients suffering from HCV than would any individual peptide.

Neither Document D2, nor any other prior art, provided any information on what mixtures of peptides would be suitable. From the many potential mixtures, the claimed ones had advantageous properties that could not be foreseen on the basis of any prior art. Therefore, their provision involved an inventive step.

X. The respondent's arguments in writing and during the oral proceedings, insofar as they are relevant to the present decision, may be summarized as follows:

Main request

- Document D2 was the closest prior art document.

- The comparative experiments of the appellant aimed at demonstrating an unexpected effect of the claimed peptides could not be taken into account because the tests were not reliable for several reasons.

- The problem to be solved could thus only be formulated as the identification of further HCV-epitope-containing peptides.

- In order to solve this problem a person skilled in the art would start with the "long" HCV clones from the table on page 32 of document D2 and prepare a series of shorter peptides which he would screen for their antigenic reactivity as taught on pages 14 and 15 of document D2.

- Clones CA279a and CA290a of the table were especially good candidates for preparing further peptides because they were qualified as "very immunogenic" on page 31 of document D2, so that the skilled person would have every expectation of success.

- By doing a systematic routine check for such shorter peptides taught on pages 14 and 15 of

document D2, the skilled person would inevitably arrive at the subject-matter of claim 1.

– In view of the explicit suggestion in document D2 that shorter peptides would be diagnostically useful, document D16 would not deter the skilled person from looking for less than full-length HCV proteins.

First, second and third auxiliary requests

– The same argument for lack of inventive step as in the case of the main request also applied to the subject matter of claim 1 of each of these requests, the argument applying to part (a) of claim 1 of the main request, which subject matter was still claimed in these other requests.

Final auxiliary request (auxiliary request 8)

– No objections were raised to this request.

XI. Requests

The appellant (patentee) requested that the decision under appeal be set aside and the patent be maintained as main request on the basis of auxiliary request 3 submitted at oral proceedings on 16 February 2005 or as auxiliary requests on the basis of auxiliary request 5, 6 or 7 as filed on 14 January 2005 or of auxiliary request 8 submitted at oral proceedings on 16 February 2005.

The respondent (opponent) requested that the appeal be dismissed.

Reasons for the Decision

Main request

1. Since no other objections were raised with regard to this request, inventive step is the only issue to be decided.

Background information

2. NANBH is the abbreviation for non-A, non-B hepatitis, a disease distinguishable from other forms of viral-associated liver diseases including that caused by, for example, hepatitis A virus, hepatitis B virus and delta hepatitis virus as well as the hepatitis induced by cytomegalovirus or Epstein-Barr virus. NANBH is, for example, caused by infection with hepatitis C virus (HCV, formerly called NANBV).

Closest prior art

3. The parties have both submitted that document D2 relating to NANBV diagnostics and vaccines is the closest prior art document, and the Board agrees.

4. Document D2 discloses on page 32 a table with 17 clones encoding HCV polypeptides, and gives information on the DNA sequence of these clones and the polypeptides thereby encoded. All clones of the table are said to have "proven reactivity with sera from NANB patients."

Amongst the 17 clones are clones CA279a and CA290a encoding, respectively, amino acids 1 to 84 and 9 to 177 of the, at that time, putative HCV core peptide, whose amino acid sequence is given in Figure 17. Five of the clones of the table on page 32 are described on page 31, lines 47-49 as "very immunogenic in that antibodies to HCV epitopes in these polypeptides were detected in many different patient sera". Amongst these five are clones CA279a and CA290a.

5. The appellant's argument that the teaching in document D2 on the immunogenicity of clones of the table on page 32 cannot be relied on because one of them, namely clone 33c, which is also one indicated as particularly immunogenic on page 31, covered a region in which it was impossible to find diagnostically significant short peptides is not relevant to the assessment of inventive step starting from document D2 because, even if this were true in respect of clone 33c, there is no evidence, certainly none on file, that this was information available to the skilled person before the filing date of the patent in suit. Such an unknown result thus could not have influenced the skilled person's initial attitude vis-à-vis document D2.

6. Document D2 discloses on pages 15 and 16 a list of peptides being fragments of the polypeptides encoded by the clones of the table on page 32. Whether this part of the disclosure was a technical teaching that the listed fragments contained epitopes, or whether it was there merely to illustrate the way in which a polypeptide can be divided into fragments for an antigenicity screening assay, or whether it was of no technical value at all was in dispute between the

parties. The Board considers it impossible to say that it has no technical value, but will treat these passages as merely illustrating how clones such as given in the table on page 32 could be divided into fragments for further screening.

7. The Board thus considers that when looking for further HCV peptides for use in HCV diagnostics or vaccines, the skilled person looking at document D2 would start from the clones disclosed in the table on page 32.

8. The following considerations relate to the subject-matter of part (a) of claim 1 because it is common to all requests except the final auxiliary request.

9. Claim 1, part (a) of the patent in suit relates to peptide sequences consisting of a "defined core sequence" optionally extended at the N- and C terminus by up to 60 amino acids. The extensions may also include units which are not standard amino acid residues. Seven possibilities are given for the defined core sequence: (I) corresponds to amino acids 1-20 in Figure 17 of document D2, except that at position 4 isoleucine appears for asparagine; (II) corresponds to amino acids 7-26 of Figure 17 with the variants at positions 9 and 11 being arginine and threonine; (IIA) corresponds to amino acids 8-18 of Figure 17, again with the variants at positions 9 and 11 being arginine and threonine; (III) corresponds exactly to amino acids 13-32 of Figure 17; (IV) corresponds to amino acids 37-5 of Figure 17 except that at position 45 there is glutamic acid for glycine; (V) corresponds to amino acids 49-68 of Figure 17 except that at position 68 there is alanine for valine; (VI) corresponds to amino

acids 61-80 of Figure 17 except that at position 68 there is alanine for valine; and finally (VII) corresponds exactly to amino acids 73-92 of Figure 17.

The patent in suit demonstrates reactivity of the seven un-extended core peptides with sera of HCV-infected patients.

10. In the course of the appeal proceedings the appellant referred to comparative tests submitted during examination and opposition proceedings in order to demonstrate unexpected properties of the claimed peptides. The reactivity of the un-extended core peptides of claim 1 with sera of HCV-infected patients was compared to the reactivity with the same sera of peptides from the list on page 15 of document D2, but not to the reactivity with the peptides of the table on page 32. For the Board to be able to recognize an improvement in relation to reactivity of the claimed peptides with sera of patients compared to what is described for peptides disclosed in document D2, the comparison should be with those peptides which are described in document D2 as being reactive with sera of patients. Document D2 only described that the peptides of the table on page 32 had reactivity with sera of patients, but not that all the peptides of the list on page 15 had such reactivity. The tests carried out by the appellant not having been made by way of comparison to the peptides of the table on page 32 stated to have reactivity, the test thus cannot be taken as establishing any improvement of the claimed peptides over the prior art. This conclusion renders a further discussion on the reliability of appellant's comparative data unnecessary.

11. Hence, the problem to be solved in view of the closest prior art can only be regarded as being the provision of further HVC-epitope containing peptides.

12. The Board considers the data in the patent in suit disclosing the immunogenic reactivity of some of the peptides covered by part (a) of claim 1 is sufficient to make it credible that the problem underlying the patent in suit has been solved by the subject matter of claim 1. No allegation to the contrary has been made by the respondent (opponent).

13. Since the present reasoning is focussed on part (a) of claim 1, in a first step the question to be answered for the evaluation of inventive step is what would a skilled person derive from the prior art in an obvious way as a solution to the above formulated problem, and would the solution(s) so derived fall under part (a) of claim 1, thus depriving claim 1 of inventive step.

14. Due to the proviso at the end of part (a) of claim 1 that when Y or Z-X are (an) amino acid(s) they are different from any naturally occurring HCV flanking regions, the peptides claimed in part (a) of claim 1 have no more than a stretch of 20 (peptides I, II, III-VII) or 11 (peptide IIA) amino acid residues in common with naturally occurring HCV residues. However, in the patent in suit no technical significance is attached to this length feature, nor was it argued before the Board that any technical significance attaches to this feature.

15. In the context of the preparation of antigenic polypeptides it is suggested in document D2 on page 14 that "in addition to full-length viral proteins, polypeptides comprising truncated HCV amino acid sequences encoding at least one viral epitope are useful as immunological reagents". Furthermore, it is stated on page 15 that the size of these truncated HCV sequences is "at least about 10, 12 or 15 amino acids up to a maximum of about 20 or 25 amino acids". Also the use of an 11mer is contemplated in document D2 for use in the screening method (see for example peptides AA35-AA45, AA65-AA75, AA80-AA90 on page 15). Thus, document D2 contains a clear pointer to using immunogenic peptides shorter than those explicitly disclosed in the table on page 32 of document D2 in immunoassays.

16. Moreover, document D2 discloses on page 15 a method by which further, epitope-containing peptides, namely those truncated with respect to the "long" sequence clones of the table on page 32 can be identified:

"Truncated HCV amino acid sequences comprising epitopes can be identified in a number of ways. For example, the entire viral protein sequence can be screened by preparing a series of short peptides that together span the entire protein sequence. An example of antigenic screening of the regions of the HCV polyprotein is shown infra. In addition, by starting with, for example 100mer, polypeptides, it would be routine to test each polypeptide for the presence of epitope(s) showing a desired reactivity and then testing progressively smaller and overlapping fragments from an identified 100mer to map the epitope of interest. Screening such

peptides in an immunoassay is within the skill of the art".

17. It is uncontested by the parties that such a method could be carried out at the time of the filing of the patent in suit in a routine manner.

18. Given that document D2 teaches in the context of preparation of truncated HCV amino acid sequences as immunological reagents (last paragraph of page 14) that "it is usually desirable to select HCV sequences of at least about 10, 12 or 15 amino acids, up to a maximum of about 20 to 25 amino acids" (first paragraph on page 15), and that furthermore, document D2 teaches on page 11 that an epitope consists of at "least 5 such amino acids, and more usually, consists of at least 8-10 such amino acids.", it is the Board's view that someone wishing to solve the problem as stated in point 11 above, would systematically investigate what sequence fragments of lengths between 10 and 25 amino acid residues over the length of the sequence given in Figure 17 of document D2 were reactive with patient sera. This, by mere routine work, would identify all amino acid fragments which were so reactive, including all sequences of length 11 or 20 amino acids which were so reactive, and thus also sequences (II), (IIA), (III) and (VII) of part (a) of claim 1.

19. Systematically applying the method to identify all possible truncated sequences of lengths between 10 and 25 would involve a lot of work, but is of a routine nature. Where the problem to be solved is to find alternatives, it must however be assumed that all

routine work to find alternatives already hinted at in the prior art will be carried out.

20. Since the method disclosed in document D2 involves the preparation of a panel of peptides as well as the testing of their antigenicity, the immediate result of it is knowledge about the immunogenicity of each of the prepared peptides. Hence the appellant's argument that immunogenicity of a given peptide cannot be reliably predicted thus lowering expectation of success of the skilled person when applying the method does not apply.

Therefore, given that the clones containing longer sequences were reactive, the skilled person would be confident that the method disclosed in document D2 would achieve success.

21. In view of the explicit suggestion in document D2 that shorter peptides would be diagnostically useful, the Board cannot agree with the view of the appellant that the statement on page 231 of document D16 that "the authentic core proteins of HCV [...] will have to be evaluated for use as an antigen" would deter the skilled person from looking for less than full-length HCV proteins as diagnostic agents. Further even document D16 discloses immunogenic activity of a truncated peptide consisting of amino acids 39 to 74 of the core protein.

22. Thus, the Board concludes that since the scope of part (a) of claim 1 includes peptides II, IIA, III, and VII which are derivable by the skilled person in an obvious manner by applying the teaching of document D2, claim 1 does not fulfil the requirements of Article 56 EPC.

23. In view of the above conclusion questions like whether appending a linker, the sort of linker or whether variations are obvious or not need not be considered.

First, second and third auxiliary requests

24. Claim 1 of each of the first, second and third auxiliary requests is directed to inter alia the subject matter of part (a) of claim 1 of the main request, and for the reasons given above in connection with claim 1, part (a) also fails to meet the requirements of Article 56 EPC on obviousness.

Final auxiliary request (auxiliary request 8)

25. The respondent neither argued against the late filing of this request nor did he raise any formal or substantive objections. The Board thus exercises its discretion pursuant to Article 111(1) EPC itself to decide the case.

Article 123 EPC

26. Claim 1 is the same for all contracting states. Basis for the peptide composition containing a mixture of peptides II, III, V, IX and XVIII or a mixture of peptides I, III, V, IX, XVIII is found in examples B, C and D. The subject matter of claim 1 of this request falls within the scope of claim 1 as granted. Thus the requirements of Article 123 EPC are met.

Articles 54 and 56 EPC

27. Peptides IX and XVIII relate to amino acids 1694-1713 and 2299-2318 of the HCV putative amino acid sequence, locations remote from those of peptides I, II, III and V. Thus claim 1 of this request relates to mixtures of peptides with epitopes some of which are far removed from each other in the amino acid sequence. Novelty has not been challenged by the respondent, and the Board sees no reason to do so.

28. The closest prior art document is also for this request considered to be document D2 disclosing individual HCV-derived peptides as diagnostic means. Accordingly, the problem to be solved can be formulated as the provision of an optimized HCV-detection system which reacts with a larger variety of sera from different patients suffering from HCV-induced hepatitis than would any individual peptide.

29. Examples B, C and D with reference to Figures 2 and Tables 4 and 5 of the patent in suit disclose that the claimed mixtures detect more sera than any of the individual peptides, and also more than some other mixtures of peptides tested. The problem can thus be regarded as solved.

30. Starting from document D2, the Board can derive no suggestion either from document D2 itself or from any other document to suggest solving the problem by using the mixtures now claimed. Thus, the presence of an inventive step for the subject-matter of claim 1 is acknowledged. Inventive step for the other claims can be acknowledged on the same grounds.

31. As in the case of the granted claims for the various Contracting States, the set of claims for the Designated States ES and GR differs from the of claims for the other Designated States by the additional presence of process claims 14 to 23. As these claims correspond to product claims 1 to 3, 6, 8 and 9 to 13, and as a process for the preparation of an inventive product will already derive its inventiveness from the inventiveness of the product, the set of claims for ES and GR as a whole can also be regarded as meeting the requirements of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The matter is remitted to the first instance with the order to maintain the patent on the basis of the claims of auxiliary request 8 submitted at oral proceedings on 16 February 2005 and a description still to be adapted thereto.

Registrar: Chair:

P. Cremona U. Kinkeldey