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D E C I S I O N
of 18 November 1999

Case Number: T 0824/94 - 3.3.4

Application Number: 85401799.3

Publication Number: 0178978

IPC: C12N 15/49

Language of the proceedings: EN

Title of invention:
Cloned DNA sequences, hybridizable with genomic RNA of lymphadenopathy-associated virus (LAV)

Patentee:
Institut Pasteur, et al

Opponent:
Chiron Corporation

Headword:
LAV/INSTITUT PASTEUR

Relevant legal provisions:
EPC Art. 123(2), (3), 84, 83, 87, 54, 56

Keyword:
"Main request - added subject-matter (yes)"
"Auxiliary request - added subject-matter (no)"
"Insufficiency of disclosure (no)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
T 0626/91

Catchword:
-

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Case Number: T 0824/94 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 18 November 1999

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 9 August 1994 concerning maintenance of European patent No. 0 178 978 in amended form.**

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: R. E. Gramaglia
S. C. Perryman

Summary of Facts and Submissions

I. European patent No. 0 178 978 (application No. 85 401 799.3) claiming priority of 19 September 1984 (GB 8423659), was filed on 17 September 1985 with the following claims inter alia:

"1. A cloned DNA which contains a DNA which is hybridizable with the genomic RNA of the LAV viruses or a fragment of said hybridizable DNA."

"2. The DNA of claim 1 which is a recombinant of said hybridizable DNA or DNA fragment hybridizable with the genomic RNA of the LAV virus."

"3. The DNA of claim 1 or 2 wherein said hybridizable DNA or DNA fragment is a cDNA."

In the description as filed at page 1, lines 28 to 35, it was stated that the term LAV viruses was used also to cover HTLV-III and ARV.

II. During examination there was cited under Article 54(3) EPC:

document (1): EP-A-0 173 529

applied for 19 August 1985 claiming priority from 22 August 1984 and designating the same Contracting States as the patent in suit. Document (1) and its priority document referred to a H9/HTLV-III producing cell line, and three cDNA clones of HTLV-III all deposited before the priority date of the patent in suit, and a method defined in its claim 5 as:

"A process for the molecular cloning and expression of cDNA sequence of HTLV-III consisting essentially of

isolating total cellular mRNA from H9/HTLV-III cells;

forming double-stranded cDNA from said mRNA and inserting said double-stranded cDNA into a phage lambda to form a recombinant DNA molecule;

hybridizing said recombinant DNA molecule with a radio-labelled probe;

removing cDNA from said molecules and inserting said cDNA into a suitable plasmid; and

transfecting said plasmids into a suitable host cell capable of expressing HTLV-III DNA sequence."

III. The patent in suit was granted on the basis of 24 claims. Claims 1, 3, 8 and 10 to 13 as granted read as follows:

"1. A cloned DNA which contains a DNA corresponding to the LAV retroviral genome contained in λJ19 (CNCM I-338)"

"3. A cloned DNA which contains a DNA which consists:

- either of the 3' terminal fragment of the DNA contained in λJ19 (CNCM I-338) corresponding to the LAV retroviral genome and which has up to 2.5 kb which contains the following restriction sites in the respective orders which follow (from the 3' end to the 5' end):
  1) either HindIII, SacI, BglII,
  2) or HindIII, SacI, BglII, BglII, KpnI
  3) or HindIII, SacI, BglII, BglII, KpnI, XhoI, BamHI, HindIII, BglII,

- or of a corresponding cloned 3' terminal DNA fragment corresponding to the LAV retroviral genome which hybridizes with the preceding one under stringent conditions comprising performing the hybridization on a filter at 68°C in 1 x Denhardt solution, 0.5% SDS, 2 x SSC, 2mM EDTA, probe: ^{32}P nick-translated LAV insert of pLAV 13 at > 10^8 cpm/µg and washing the filter 2x30 minutes in 0-1 SSC, 0.1 % SDS at 68°C."

"8. The DNA of claims 1 or 2, wherein said DNA contains the following series of restriction sites:

Hind III	0
Sac I	50
Bam HI	460
Hind III	520
Bam HI	600
Pst I	800
Hind III	1100
Bgl II	1500
Kpn I	3500
Kpn I	3900
Eco RI	4100
Eco RI	5300
Sal I	5500
Kpn I	6100
Bgl II	6500
Bgl II	7600
Hind III	7850
Bam HI	8150
Xho I	8600
Kpn I	8700
Bgl II	8750
Bgl II	9150
Sac I	9200
Hind III	9250."

"10. A cloned DNA fragment whose sequence corresponds to the part of the DNA of claim 8 which extends from approximately Kpn I (6100) to approximately Bam HI (8150) thereof or a DNA fragment of the same length which hybridizes with the first one under stringent conditions comprising performing the hybridization on a filter at 68°C in 1 x Denhardt solution, 0.5 % SDS, 2 x SSC, 2mM EDTA, probe: ^{32}P nick-translated LAV insert of pLAV 13 at > 10^8 cpm/µg and washing the filter 2 x 30 minutes in 0-1 SSC, 0.1 % SDS at 68°C."

"11. A cloned DNA fragment whose sequence corresponds to the part of the DNA of claim 8 which extends from approximately Kpn I (3500) to approximately Bgl II (6500) thereof or a DNA fragment of the same length which hybridizes with the first one under stringent conditions comprising performing the hybridization on a filter at 68°C in 1 x Denhardt solution, 0.5 % SDS, 2 x SSC, 2mM EDTA, probe: ^{32}P nick-translated LAV insert of pLAV 13 at > 10^8 cpm/µg and washing the filter 2 x 30 minutes in 0-1 SSC, 0.1% SDS at 68°C."

"12. A cloned DNA fragment whose sequence corresponds to the part of the DNA of claim 8 which extends from approximately Pst I (800) to approximately Kpn I (3500) thereof or a DNA fragment of the same length which hybridizes with the first one under stringent conditions comprising performing the hybridization on a filter at 68°C in 1 x Denhardt solution, 0.5 % SDS, 2 x SSC, 2mM EDTA, probe: ^{32}P nick-translated LAV insert of pLAV 13 at > 10^8 cpm/µg and washing the filter 2 x 30 minutes in 0-1 SSC, 0.1 % SDS at 68°C."

"13. A cloned DNA fragment whose sequence corresponds to the part of the DNA of claim 8 which extends from approximately Bgl II (6500) to approximately Bgl II (9150) thereof or a DNA fragment of the same length which hybridizes with the first one under stringent

conditions comprising performing the hybridization on a filter at 68°C in 1 x Denhardt solution, 0.5 % SDS, 2 x SSC, 2mM EDTA, probe: ^{32}P nick-translated LAV insert of pLAV 13 at > 10^8 cpm/µg and washing the filter 2 x 30 minutes in 0-1 SSC, 0.1% SDS at 68°C."

IV. Notice of opposition was filed by the appellant (opponent). Revocation of the patent in its entirety was requested on the grounds of Articles 100(a), 100(b) and 100(c) EPC, i.e. lack of novelty (Article 54 EPC), lack of inventive step (Article 56 EPC), insufficiency of disclosure (Article 83 EPC) and added subject-matter (Article 123(2) EPC).

V. By its decision given orally on 22 July 1994 and issued in writing on 9 August 1994, the opposition division maintained the patent on the basis of claims 1 to 21 filed during the oral proceedings.

VI. The appellant (opponent) filed a notice of appeal against this decision and a Statement of Grounds of Appeal. The respondent (proprietor of the patent in suit) filed counterarguments. The following documents are referred to in the present decision in addition to document (1):

(A1) Wain-Hobson S. et al., Cell, Vol. 40, pages 9 to 17 (1985)

(3) Declaration of Dr M.S. Urdea on behalf of the appellant dated 11 May 1991

(5) Ratner L. et al., Nature, Vol 313, pages 277 to 284 (January 1985)

(7) Sanchez-Pescador R. et al. in Aids (papers from Science 1982-1985), pages 410 to 428 (February 1985)

(14) Shaw G.M. et al., Science, Vol. 226, pages 1165 to 1171 (7 December 1984)

(16)-(23) Documents pertaining to the re-deposit of λJ19

VII. On 24 February 1999, the board issued a communication pursuant to Article 11(2) of the Rules of Procedure of the Boards of Appeal, expressing its provisional opinion.

VIII. Oral proceedings were held on 12 May 1999, during which the respondent submitted a new main request and an auxiliary request, replacing all previously filed requests. After deliberation by the board, the Chairwoman announced that the debate was closed and that the decision would be issued in writing on due course.

IX. Claims 1 and 3 to 6 of the new main request read as follows (amendments over granted claim 1 are shown in bold):

"1. A cloned DNA which contains a DNA corresponding to the LAV retroviral genome contained in λJ19 (CNCM I-338), **said cloned DNA including LTR elements U3, R and U5 of said retroviral genome.**"

"3. A cloned DNA which contains a DNA which consists:

- either of a 3' terminal fragment of the DNA contained in λJ19 (CNCM I-338) **including the R and U3 regions of the 3' LTR**, and which has up to 2.5 kb which contains the following restriction sites in the respective orders which follow (from the 3' end to the 5' end):

1) either Hind III, Sac I, Bgl II,
2) or Hind III, Sac I, Bgl II, Bgl II, Kpn I,
3) or Hind III, Sac I, Bgl II, Bgl II, Kpn I, Xho I, Bam HI, Hind III, Bgl II,

- **or a corresponding fragment which hybridizes under stringent hybridization and washing conditions with a cloned 3' terminal fragment of up to 2.5 kb of the cloned DNA contained in λJ19 (CNCM I-338) which includes the sites Hind III, Sac I, Bgl II, Bgl II, Kpn I, Xho I, Bam HI, Hind III, Bgl II, and which is free of the following restriction sites Eco RI, Nru I, Pvu I, Sal I, Sma I, Sph I, Stu I and XBa I."**

"4. A cloned DNA fragment whose sequence corresponds to the part of the DNA of λJ19 which extends from approximately Kpn I (6100) to approximately Bam HI (8150) thereof

- **or a corresponding fragment which hybridizes under stringent hybridization and washing conditions with a cloned 3' terminal fragment of up to 2.5 kb of the cloned DNA contained in λJ19 (CNCM I-338) which includes the sites Hind III, Sac I, Bgl II, Bgl II, Kpn I, Xho I, Bam HI, Hind III, Bgl II, and which is free of the following restriction sites Eco RI, Nru I, Pvu I, Sal I, Sma I, Sph I, Stu I and XBa I."**

"5. A cloned DNA fragment whose sequence corresponds to the part of the DNA of λJ19 which extends from approximately Kpn I (3500) to approximately Bgl II (6500) thereof **or a corresponding DNA fragment which hybridizes under stringent hybridization and washing conditions with a corresponding fragment of λJ19 which extends from approximately Kpn I (3500) to approximately Bgl (6500).**"

"6. A cloned DNA fragment whose sequence corresponds to the part of the DNA of λ**J19** which extends from approximately Pst I (800) to approximately Kpn I (3500) thereof **or a corresponding DNA fragment which hybridizes under stringent hybridization and washing conditions with a corresponding fragment of λJ19 which extends from approximately PstI (800) to approximately KpnI (3500)**."

X. Claims 1 and 3 to 6 of the auxiliary request read as follows (amendments over granted claim 1 are shown in bold):

"1. A cloned DNA which contains a DNA corresponding to the LAV retroviral genome contained in λJ19 (CNCM I-338), **said cloned DNA including LTR elements U3, R and U5 of said retroviral genome.**"

"3. A cloned DNA which contains a DNA which consists:

- either of the 3' terminal fragment of the DNA contained in λJ19 (CNCM I-338) **including the R and U3 regions of the 3' LTR**, and which has up to 2.5 kb which contains the following restriction sites in the respective orders which follow (from the 3' end to the 5' end):

  1) either Hind III, Sac I, Bgl II,
  2) or Hind III, Sac I, Bgl II, Bgl II, Kpn I,
  3) or Hind III, Sac I, Bgl II, Bgl II, Kpn I, Xho I, Bam HI, Hind III, Bgl II."

"4. A cloned DNA fragment whose sequence corresponds to the part of the DNA of λ**J19** which extends from approximately Kpn I (6100) to approximately Bam HI (8150) thereof."

"5. A cloned DNA fragment whose sequence corresponds to the part of the DNA of λJ19 which extends from approximately Kpn I (3500) to approximately Bgl II (6500) thereof."

"6. A cloned DNA fragment whose sequence corresponds to the part of the DNA of λJ19 which extends from approximately PstI (800) to approximately Kpn I (3500) thereof."

XI. The appellant submitted in writing and at the oral proceedings inter alia the following arguments still relevant to the requests finally put forward on appeal:

Article 84 EPC

- The wording "corresponding to" rendered claim 1 of both requests unclear.

- The amendments to claims 3, 4, 5 and 6 of the main request made these claims unclear.

Article 123(2) EPC

- The hybridization conditions referred to in claims 3 to 6 of the main request found no support in the application as filed. There was also no basis in the application as filed for the disclaimer "which is free of the following restriction sites Eco RI, Nru I, Pvu I, Sal I, Sma I, Sph I, Stu I and XBa I" in these claims.

Article 123(3) EPC

- The scope of claims of 3 and 4 of the main request had been broadened. In the corresponding claims 3 and 10 as granted, the probe of reference was the

pLAV 13 insert, whereas in claims 3 and 4 of the main request, the length of the probe of reference had been changed. However, the length of the reference DNA was a critical factor for defining the scope of a claim to DNAs capable of hybridizing to a DNA probe.

Article 83 EPC

- In the absence of a correct identification of the LTR elements U3, R and U5 (Figure 2 of the patent in suit was an imprecise sketch) and guidance as to what concentrations of the hybridization reagents to use, the skilled person was prevented from knowing whether (s)he was in possession of a DNA of claim 1. This uncertainty led to an insufficiency under Article 83 EPC on the reasoning given eg. in decision T 626/91 of 5 April 1995.

- It was impossible to reproduce the invention because sequence of the clone identified as λJ19 in the priority document (Figures 1 and 2) was not the same as the clone referred to as λJ19 in the European patent application (Figures 3 and 4 to 11), since a series of restriction sites present in Figure 2 of the priority document were missing in Figures 3 and 4 to 11 of the patent specification (eg no Bam HI restriction sites at 460 and 600 nor a Bgl II restriction site around 9150 could be found in Figures 3 and 4 to 11 of the patent specification). It had been admitted by the respondent that in the sequenced clone of Figures 3 and 4 to 11 of the patent specification the Bgl II restriction site at 9150 was not there.

This restriction site was however in the originally deposited λJ19 claimed in claim 1, and an essential feature of the cloned DNA of claim 3, so certainly the subject-matter of these claims was not enabled by the deposited clone.

- Claims 5 and 6 of the auxiliary request related to restriction fragments cut from the Kpn I site around nucleotide 3500. However, the restriction site Kpn I (GGTACC) was not to be found in Figures 4 to 11 of the patent in suit, which was thus not enabling for these fragments.

Article 87 EPC

- For the same reasons the clone identified as λJ19 in the priority document was not the same as the clone referred to in the European patent application as filed, the latter could not validly claim the priority date of 19 September 1984.

- Any particular clone termed λJ19 was not a static entity but was subject to variation or drift. Therefore this could have jeopardized the validity of a re-deposit according to Rule 28a EPC since it was not sure that the re-deposited λJ19 (see documents (16)-(23)) was the same as the one used for generating Figure 2 of the priority document, Figure 3 or Figures 4 to 11 of the patent in suit.

Novelty

- As a consequence of the finding under Article 87 EPC, the relevant date for evaluating the novelty of the claims was the European filing date of 17 September 1985. The claims lacked novelty over intermediate documents (A1), (5) and (7) published before that date.

- The skilled person was unable to locate the "LTR elements", the only feature which conferred novelty on claim 1 over document (1). But an undefined feature could not make a claim novel.

- Claims 3, 4, 5 and 6 as amended were not novel over document (1).

Inventive step

- In view of the failure to comply with the requirements of Article 87 EPC, the subject-matter of the claims was obvious in view of intermediate documents (A1), (5) and (7).

XII. In support of his requests, the respondent submitted in writing and at the oral proceedings the following arguments:

Article 84 EPC

- Lack of clarity was not a ground of opposition.

- For the purpose of questioning the novelty, the scope of claim 1 was clear to the appellant, despite of the word "corresponding to".

Article 123(2) EPC

- The basis in the application as filed for the disclaimer "which is free of the following restriction sites Eco RI, Nru I, Pvu I, Sal I, Sma I, Sph I, Stu I and XBa I" in claims in claims 3 to 6 of the main request was to be found on page 3, lines 30 to 33.

Article 123(3) EPC

- There had been no broadening of the scope of claims 3 and 4 over the corresponding granted claims.

Article 83 EPC

- The patent in suit provided all the necessary information as to how a cDNA and its restriction fragments could be obtained from the deposited virus.

Article 87 EPC

- Sequencing was done somewhat later on "descendants" of the deposited clone λJ19, which could have undergone some minor polymorphic changes. These point mutations were of no significance for the purpose of defining the invention since a mutant virus was not a new virus and its genome was hybridizable with the deposited one. Further, restriction enzymes might not have been pure at that time; but also this deficiency was not relevant.

Novelty

- For the purpose of evaluating the novelty, exact localization of the "LTR elements" was not relevant. The skilled person had rather to know that they were there.

XIII. The appellant (opponent) requested that the decision under appeal be set aside and that the patent No. 0 178 978 be revoked.

The respondent (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the new main request or on the basis of the auxiliary request, both submitted at oral proceedings on 12 May 1999.

Reasons for the Decision

1. The appeal is admissible

2. For ease of understanding the critical issues to be considered in this case, it seems worth remarking, before considering in detail the claims put forward on appeal, that the problems which have arisen on this patent at the application stage, the opposition stage and now on appeal all are due to the existence of document (1), a European application for a very similar invention having a priority one month earlier than that of the patent in suit. Document (1) can thus only be considered as prior art for the purposes of novelty under Article 54(3) EPC, but cannot be taken into account when considering inventive step (Article 56 EPC). Any amendments made to establish novelty of the claims over document (1) must in accordance with the established case law of the boards of appeal be clearly

and unambiguously based on the text of the application as filed, the strict standard applied by the boards when considering the requirements of Article 123(2) EPC. The standard applied is the same as that established by the boards of appeal when considering whether a prior art document clearly and unambiguously discloses something that destroys the novelty of a claim. Only by applying the same standard in each case can a result adequate to both the earlier and the later applicant be achieved. The later applicant is not allowed to amend his claims to cover possible embodiments that the later applicant alleges would obviously also be understood by the skilled person from the original application, if such embodiments are not clearly and unambiguously disclosed. If such a more generous approach to Article 123(2) EPC were applied, it would require the novelty-destroying content of an earlier application to be interpreted, contrary to the present practice of the boards of appeal, to cover obvious modifications which the skilled person could derive for himself from the earlier application. The result of such a changed approach would be undesirable uncertainty, possibly leading to double protection in the case where both patents remain in force.

Main request

Article 84 EPC

Claim 1

3. The appellant has objected that the word "corresponding" in claim 1 renders the scope of the claim unclear. This word was not introduced by an amendment after grant, so prima facie, no objection appears to be open under this Article on appeal. But even if it were, in the context of both claim 1 and the description, usage of this word appears to be in the

narrow sense of base to base correspondence, subject to the allowable variations which would not substantially alter their capability of also hybridizing with the LAV retroviral genomes, as understood by a person skilled in the art. These allowable variations are spelled out for DNA fragments in the passage appearing at page 6, lines 2 to 6, of the application as filed (page 5, lines 15 to 20): "It is of course to be understood that fragments which would include some deletions or mutations which would not substantially alter their capability of also hybridizing with the LAV retroviral genomes are to be considered as forming obvious equivalents of the DNA fragments more specifically referred to..". This passage no longer appears in the patent as granted, but variations on these lines must reasonably still be considered as included in the claim.

Claim 3

4. The second half of this claim has been substantially amended compared to the granted claim 3 from which it is derived. The amended wording is open to two interpretations, the first being:

"or a corresponding fragment which hybridizes under stringent hybridization and washing conditions with a cloned 3' terminal fragment of up to 2.5 kb of the cloned DNA contained in λJ19 (CNCM I-338) which includes the sites Hind III, Sac I, Bgl II, Bgl II, Kpn I, Xho I, Bam HI, Hind III, Bgl II, and which is free of the following restriction sites Eco RI, Nru I, Pvu I, Sal I, Sma I, Sph I, Stu I and XBa I." Here the cloned 3' terminal fragment is defined by the presence or absence of certain restriction sites. The second interpretation is (reference numerals added in square brackets by the board):

"or a corresponding fragment

[1] which hybridizes under stringent hybridization and washing conditions with a cloned 3' terminal fragment of up to 2.5 kb of the cloned DNA contained in λJ19 (CNCM I-338)

[2] which includes the sites Hind III, Sac I, Bgl II, Bgl II, Kpn I, Xho I, Bam HI, Hind III, Bgl II,

[3] and which is free of the following restriction sites Eco RI, Nru I, Pvu I, Sal I, Sma I, Sph I, Stu I and XBa I."

Here it is the "corresponding fragment" which is defined by hybridization and washing conditions and by the presence or absence of certain restriction sites. The first interpretation seems the more likely. Further the word "corresponding" has lost the referent it had in granted claim 3 reading "...corresponding 3' terminal fragment corresponding to a LAV retroviral genome which hybridizes with the preceding one".

Claim 4

5. This claim is derived from claim 10 as granted. Similar comments apply to the second half of the claim beginning with "... or corresponding fragment..." as for claim 3.

Claims 5 and 6

6. These are derived from claims 10 and 11 as granted. Their second halves have been amended in like manner, there now being introduced into each a reference to "a corresponding fragment" without clear indication of what is referred to.

7. However, in view of the conclusions reached as to the requirements of Article 123 EPC below, it is unnecessary for the board to decide whether the uncertainties introduced into the amended claims are such that the main request must already be rejected for failing to satisfy Article 84 EPC.

Article 123(2) EPC

8. The second parts of each of Claims 3, 4, 5 and 6 relate to fragments which hybridize with a fragment of λJ19. However, in the application as filed there are mentioned only "DNA fragments hybridizable with the RNA of LAV (see page 2, lines 28 to 29 and page 5, line 28), "fragments having the capability of hybridizing with the LAV retroviral genome" (see page 5, last line to page 6 line 7), and claims 1 and 2 as filed (see Section I supra)). There is no mention of selection of fragments hybridizable with pLAV 13. The reference on page 11, first full paragraph to fragments of λJ19 and λJ81 detected and respectively not detected by pLAV 13 is to identify where restriction sites are, and not in connection with the selection of a particular subset of cloned DNA for the purpose of the invention. It may be that the skilled person might derive such a subset for him- or herself, but there is here no clear and unambiguous disclosure of this for the purposes of Article 123(2) EPC. There is also no expressis verbis mention of fragments hybridizable with the restriction fragments Kpn I (6100) to approximately BamH I (8150) (claim 4), Kpn I (3500) to approximately Bgl II (6500) (claim 5) and from approximately Pst I (800) to approximately Kpn I (3500) (claim 6) in the application as filed. These fragments also cannot be implicitly derived therefrom because it is not sufficient that these sub-classes of "hybridizable fragments" referred to in claims 4 to 6 belong **conceptually** to the broader class of "fragments having

the capability of hybridizing with the LAV retroviral genome", if there is no pointer in the application as filed to these individual sub-classes of "hybridizable fragments". The subject-matter of claims 3 to 6 thus does not meet the requirements of Article 123(2) EPC.

Article 123(3)

Claim 3

9. Claim 3, second half, as granted referred to a "..corresponding 3' terminal DNA fragment corresponding to a LAV retroviral genome" and to hybridization under stringent conditions including washing the filter in 0-1 SSC. In claim 3 of the main request the reference to "3' terminal" has been omitted, as has been the reference to washing in 0-1 SSC. Both changes appear to widen the range of fragments which would meet the conditions of the claim, and the change is thus contrary to Article 123(3). While the omission of 0-1 SSC avoids the dispute between the parties as to the meaning of this feature, it being accepted by the respondent that this was probably an error for 0.1 SSC, because of the requirements of Article 123(3) EPC, simple deletion of a feature normally is not an acceptable way of putting the matter right.

Claim 4

10. Claim 4 derives from claim 10 as granted. The second half of granted claim 10 referred to a DNA of the same length as that claimed in the first half of the claim. The amended claim 4 now put forward omits this reference to the length of the fragment in the second half, and as in claim 3 discussed above omits the feature of washing in 0-1 SSC. The claim thus fails to comply with Article 123(3) EPC.

Claims 5 and 6

11. These derive from granted claims 11 and 12. In each case the same objectionable changes have been made as discussed in the immediately above paragraph in relation to claim 4. These claims thus also fail to comply with Article 123(3) EPC.

Claims 7 to 10

12. As these claims refer back to claims 3 to 6 inter alia, their scope has also been extended in way that contravenes Article 123(3) EPC.

Article 54 EPC - Novelty

13. The question of the novelty of the claim 1, and the first half of claims 3, 4, 5, and 6 will be discussed in connection with the auxiliary request.

14. Here it needs merely be briefly remarked that the second halves of claims 3, 4, 5 and 6 relating to sets of fragments that are hybridizable with other fragments, now omit any identifiable characteristics which would serve to distinguish the claimed fragments from the disclosure of document (1).

Article 113 EPC

15. The main request was put forward at a late stage of the oral proceedings. The appellants confined themselves to remarking that the claims were open to every objection possible, on the existing evidence. By putting forward the request at that late stage, the respondent deprived himself of the opportunity of preliminary reasoned comments by the board, but as objections had been raised by the appellant to the previous claims under all of Articles 84, 123(2), 123(3) and 54 EPC, the

respondent was aware of the grounds and evidence on which the patent was being objected to and had the opportunity demanded by Article 113 EPC to try and meet these.

16. The board concludes that the main request must be refused.

Auxiliary request

Article 84 EPC

Claim 1

17. The claim has been amended since grant, but not as respects the passage where the word "corresponding to" appears, but, as already explained in point 3 above, the appellant's objection as to the lack of clear meaning of "corresponding to" fails.

18. The appellant has also objected that the additional wording added namely "said cloned DNA including the LTR elements U3, R and U5 of said retroviral genome" have no support in the description and are unclear, because although Figure 2 shows that λJ19 includes all the LTR elements U3, R and U5 it is also stated (page 10, lines 30-32 as originally filed) that "Only the R/U5 boundary has been defined and other boundaries are only drawn figuratively". However this description provides sufficient support for the added wording, as while there may be doubt where the precise boundaries of all the elements are, the skilled person will certainly understand that they are all to be found in λJ19 at the position shown in Figure 2. No experimental evidence has been adduced to show that this is not in fact true for the original or re-deposited clone.

Claims 3 to 11

19. No lack of clarity or lack of support has been alleged against any changes introduced into these claims compared to the respective claims as granted, and the board sees no objections under Article 84 EPC to these claims.

Article 123(2) EPC

Claim 1

20. For the reasons already indicated in point 18 above the claim as now amended has a basis in the application as originally filed.

21. The appellant has submitted that the facts that:

(a) the originally deposited clone became non-viable and had to be replaced by the patentee in accordance with the provisions of Rule 28a EPC by a newly deposited clone from biological material maintained by the patentee and

(b) the new deposit differed from the originally deposited clone in some restriction sites

meant that the claims all of which referred directly or indirectly to the original deposit had no basis for the purpose of Article 123(2) EPC.

22. On behalf of the respondent it was stated to the depositary organisation that the re-deposit was the same as the original. There is no evidence, from experiments or otherwise, before the board to show that the re-deposit is a basis not as suitable as the original clone for the matter claimed. The board is not prepared to find that the re-deposit deprives the

claims of support, in the absence of evidence substantiating that any feature in claim 1 of the auxiliary request (see Section X supra) was changed in the re-deposit to such an extent that this clone no longer falls under the scope of claim 1.

Claim 3

23. Compared to claim 3 as granted, claim 3 of this request has been amended by deleting the words "corresponding to the LAV retroviral genome" after "λJ19 (CNMC I-338)", insertion of the words "including the R and U3 regions of the 3'LTR" and deletion of the whole alternative covered by the second half of the claim as granted.

24. As λJ19 is defined in the description as corresponding to the LAV retroviral genome, the deletion makes no difference to the content and scope of the claim. The inserted words have a basis in the description and claim 8 as originally filed.

25. The deletion of the alternative removes the objections raised by the appellant to the second half of claim 3 as granted.

Claim 4

26. Claim 4 has a basis in claims 1, 11 and 12 as filed (and as appearing in the priority document) and in the general description at pages 3 to 5. These claims did not refer specifically to the DNA sequence of λJ19 as deposited, but to "a DNA which is hybridizable with the genomic RNA of the LAV viruses", a definition under which λJ19 as deposited (and re-deposited) falls. The claim as a whole thus has a basis in the application as originally filed.

Claim 5

27. Claim 5 has a basis in claims 1, 11 and 13 as filed (and as appearing in the priority document). These claims did not refer specifically to the sequence of λJ19 as deposited, but to "a DNA which is hybridizable with the genomic RNA of the LAV viruses", a definition under which λJ19 as deposited (and re-deposited) falls. The claim as a whole thus has a basis in the application as originally filed.

Claim 6

28. Claim 6 has a basis in claims 1, 11 and 14 as filed (and as appearing in the priority document). These claims did not refer specifically to the sequence of λJ19 as deposited, but to "a DNA which is hybridizable with the genomic RNA of the LAV viruses", a definition under which λJ19 as deposited (and re-deposited) falls. The claim as a whole thus has a basis in the application as originally filed.

Claims 7 to 11

29. Claim 7 has a basis in claim 17 originally filed (and claim 17 of the priority document).

30. Claim 8 has a basis in claim 19 originally filed, and is foreshadowed in the passage of the priority document on page 13, lines 11 to 12, reading "The DNA according to the invention can be used also for achieving the expression of LAV viral antigens for diagnostic purposes..".

31. Claims 9 and 10 have a basis in claims 20 to 22 originally filed (being claims 19 to 21 of the priority document).

32. Claim 11 has a basis in claim 24 originally filed (claim 22 of the priority document).

Article 123(3) EPC

33. The scope of claims of the auxiliary request is now in every case either the same as or more limited than that of the corresponding granted claims, so that the claims of this request satisfy the requirement of Article 123(3) EPC.

Article 87 EPC

34. The right to priority is governed by Article 87 EPC, which requires that the European patent application and the priority document relate to the same invention. The appellant maintained that the claims of the auxiliary request could not rely on the claimed priority date because the clone identified as λJ19 in the priority document (Figures 1 and 2) was not the same as the clone referred to as λJ19 in the European patent application (Figures 3 and 4 to 11). It was also argued that the re-deposited λJ19 could also have been different from either of these two λJ19, and that the description would be positively misleading in relation to the re-deposited clone, the only clone now available to the public.

35. There is a verbal basis for the present claims in the priority document as discussed above in connection with Article 123(2) EPC. For the purpose of Article 87 EPC the present claims can thus be treated as relating to the same invention as the one disclosed in the priority document, and so entitled to the priority date.

Article 83 EPC

36. The fact that the Kpn I (3200) and Bgl II (9100) restriction sites are not to be found in Figures 4 to 11 of the patent in suit does not mean that the latter is not enabling for the fragments of claims 3 to 6 of the auxiliary request since these restriction sites are present in re-deposited λJ19 (CNCM I-338)(see the restriction map included in document (18)). This map also shows the presence of the restriction sites Bgl II (6500), Pst I (800), Kpn I (6100) and Bam HI (8150). Thus, the re-deposited phage λJ19 (CNCM I-338) also enables the skilled person to reproduce the restriction fragments of claims 3 to 6 of the auxiliary request. There certainly is no experimental evidence to the contrary before the board.

37. The appellant also argues under Article 83 EPC that the skilled person is not in a position to correctly identify the LTR elements and to establish under which conditions hybridization should occur and hence (s)he is prevented from knowing whether a given DNA falls under the scope of claim 1. There is no evidence before the board to substantiate that any alleged deficiencies on these lines are really such as to prevent the skilled person putting the invention into practice. This is because an exact localization of the "LTR elements" is not relevant, as long as the skilled person can establish that these "LTR elements" are present. This was possible at the priority date of the patent in suit because the LTR elements were present in other known retroviruses such as HLTV-I, HTLV-II and bovine leukemia virus (BLV) (see document (5), passage bridging l-h and r-h column on page 277 and the references cited therein).

38. Also the appellant's line of argument that the skilled person did not know under which hybridization conditions the test had to be performed, is not convincing. This is because Dr Urdea, an appellant's own expert, states that these conditions should be "stringent conditions" (see document (3), point 6). This is in line with page 10, lines 2 to 16 of the application as filed, wherein picking up seven positives on two million phage plaques with no false positive (which should always be avoided) must have of necessity been performed under stringent hybridization conditions.

39. In view of these findings, the board concludes that the claims of this request fulfil the requirements of Article 83 EPC.

Article 54 EPC

Claims 1, 3 and 11

40. The appellant's objections under Article 54 EPC are based on the assumptions (i) that the claims lacked novelty over intermediate documents (A1), (5) and (7) published before the filing date of the European patent application because the latter could not rely on the claimed priority date and (ii) that the skilled person was unable to locate exactly the "LTR elements", the only feature which, in the respondent's view, conferred novelty on claim 1 over document (1). As stated above the board accepts that all the claims are entitled to the priority date, so the line of argumentation (i) for lack of novelty fails.

41. In relation to document (1), the DNA of claims 1 and 3 are novel over the recombinant clone BH10 of document (1), which is an example of a LAV virus DNA, because the latter includes no LTR element U5 and no complete

LTR element R. This is stated expressis verbis in later document (14) taken as an expert's opinion (see page 1167, 1-h column: "We know from recent analyses that λBH-10, λBH-5/λBH-8 are incomplete viral clones that lack a short Sst I-Sst I segment of approximately 190 base pairs in the 5' LTR-leader sequence region"). Thus, also objection (ii) above (point 40) is not convincing.

42. Nor does document (1) disclose a purified RNA of LAV virus which has a size from 9.1 to 9.2 kb and which corresponds to the cDNA contained in λJ19 as deposited or re-deposited. So claim 11 is also novel over document (1).

Claims 4 to 6

43. The novelty of the restriction fragments of claims 4 to 6 of the auxiliary request have not been challenged by the appellant. The board also has to acknowledge the novelty thereof since these restriction fragments are not disclosed by document (1).

Claims 7 to 10

44. Likewise the novelty of claims 7 to 10 which directly or indirectly refer back to the novel DNA of claims 1 to 6 must be acknowledged on the basis that this DNA is novel.

45. No other documents were alleged to be novelty destroying, so the board finds that the novelty of all claims of this request has been established.

Article 56 EPC

46. The appellant's line of argument for invalidity of the patent in suit on the ground of lack of inventive step under Article 56 EPC over documents (A1), (5) and (7), published before the filing date of the European patent application but after the priority date, depended on the claims being entitled only to the European filing date. As stated above the board finds the claims entitled to the priority date and so this objection of lack of inventive step over documents (A1), (5) and (7) fails.

47. Bearing in mind that document (1) is a document according to Article 54(3) EPC and so cannot be relied on for the purpose of considering inventive step, no case for lack of inventive step remains to be considered on appeal.

48. In the judgement of the board no grounds exist under the European Patent Convention which preclude the patent being maintained on the basis of the claims of the auxiliary request. The description and drawings can remain as granted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the auxiliary request as filed in the oral proceedings on 12 May 1999.

The Registrar: The Chairwoman:

U. Bultmann U. Kinkeldey