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D E C I S I O N
of 13 November 1996

Case Number: T 0767/93 - 3.3.4

Application Number: 87302001.0

Publication Number: 0236145

IPC: C12N 15/38

Language of the proceedings: EN

Title of invention:
Processes for the production of HCMV glycoproteins, antibodies thereto and HCMV vaccines, and recombinant vectors therefor

Patentee:
Cogent Limited

Opponent:
SmithKline Beecham Biologicals SA

Headword:
HCMV/Cogent Ltd

Relevant legal provisions:
EPC Art. 54, 56, 83, 87, 88

Keyword:
"Entitlement to priority"
"Main request - novelty (yes)"
"Inventive step (no) - subject-matter of independent claim obvious"
"First auxiliary request - inventive step (yes)"

Decisions cited:
T 0081/87, T 0296/93

Catchword:
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Case Number: T 0767/93 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 13 November 1996

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office dated 6 July 1993 rejecting the opposition filed against European patent No. 0 236 145 in amended form.**

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: L. Galligani
S. C. Perryman

Summary of Facts and Submissions

I. European patent No. 0 236 145, filed on 9 March 1987 and claiming priority from three British patent applications dated 7 March 1986 (P1), 1 September 1986 (P2) and 16 December 1986 (P3), respectively, was granted on 27 March 1991 with eleven claims in the two versions for eleven Contracting States except Austria (non-AT States) and for Austria (AT) in response to European patent application No. 87 302 001.0.

II. Notice of opposition was filed against the European patent by one party that requested the revocation of the patent on the grounds of Article 100(a) to (c) EPC. During the procedure before the Opposition Division twenty-five documents were relied upon by the parties. Among them, the following are referred to in the present decision (numbering as used by the opposition division):

(2) Virology, 1984, Vol. 135, 369-378;
(3a) J.Virol., 1985, Vol. 55, No. 2, 274-280;
(3b) Virology, 1985, Vol. 145, 186-190;
(5) EP-A-0 110 385;
(6) J.Gen.Virol., 1982, Vol. 59, 111-129;
(9) J.Gen.Virol., 1986, Vol. 67, 1461-1467;
(10) EP-A-0 252 302;
(11) The EMBO J., 1986, Vol. 5, no. 11, 3057-3063;
(25) Proc.Natl.Acad.Sci. USA, 1985, Vol. 82, 1266-1270.

III. The opposition division issued on 6 July 1993 an interlocutory decision within the meaning of Article 106(3) EPC whereby the patent was maintained on the basis of claims 1 to 11 for non-AT States and

claims 1 to 11 for AT as filed on 25 May 1993, which differed from the claims as granted only in that the expression "by chemical means" was added in claim 6 (non-AT States and AT) after the word "synthesising".

Claims 1 and 6 for the non-AT States read as follows (HCMV is the acronym for human cytomegalovirus):

"1. A process which comprises expressing from a recombinant DNA vector in a suitable host organism a polypeptide capable of raising HCMV-neutralising antibodies in humans and which incorporates one or more antigenic determinants from the HCMV glycoprotein gB or gH, as represented in Figures 3 and 5 hereof for the HCMV strain AD169.

6. A process which comprises synthesising by chemical means a pol[y]peptide capable of raising HCMV-neutralising antibodies in humans and which incorporates one or more antigenic determinants from the HCMV glycoprotein gB or gH, as represented in Figures 3 and 5 hereof for the HCMV strain AD169."

Claim 2 concerned an embodiment of claim 1. Claims 3 to 5 were directed to a recombinant virus vector, to a vaccine incorporating it and to an expression vector, respectively. Claims 7 to 9 concerned a method for preparing HCMV monospecific antiserum, HCMV-specific monoclonal antibodies, and a method for purifying HCMV-specific antibodies, respectively. Claims 10 and 11 were directed, respectively, to a method of detecting HCMV-specific antibody and to a kit therefor.

IV. The opposition division considered that the claims as granted per se did not give rise to objections under Article 123(2) EPC and that the amendment introduced in claim 6 was not objectionable under the terms of Article 123(2) and (3) EPC. The opposition division

further decided that the patent in suit disclosed the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person. Moreover, since the claimed subject-matter enjoyed the first priority date, none of the cited documents affected its novelty. Inventive step was also acknowledged on the basis of the consideration that, in the light of documents (3a) and (3b), the identification of the specific HCMV DNA sequences encoding glycoprotein gB or gH within the large size genome of HCMV would have required for a skilled person undue experimentation or considerable luck.

V. The appellants (opponents) lodged an appeal against the decision of the opposition division. A new reference was filed with the statement of grounds.

On 2 December 1994, the respondents (patentees) submitted their counterarguments together with an affidavit by Professor Lenore Pereira and an auxiliary request I limited to the HCMV glycoprotein gH.

VI. On 26 July 1996, the Board issued a communication with an analysis of the case. In reply to the said communication, the appellants submitted on 13 September 1996 further arguments and a number of new documents. The admissibility at this stage of this new evidence was contested by the respondents.

VII. Oral proceedings were held on 16 October 1996 and it was announced that the order of the decision would be given in writing on 13 November 1996. During oral proceedings, the English translation of the priority document of the European patent application EP-A-0 252 302 (document (10)) was submitted. The respondents filed a new main request (claims 1 to 17 in the two versions for all non-AT states and AT) and a new first auxiliary request (claims 1 to 16 in the two

versions for all non-AT states and AT) in substitution of all previous requests on file. Claim 1 to 11 in the two versions for all non-AT states and AT filed on 2 December 1994 (see section V above) constituted the second auxiliary request.

As regards the **main request** for all non-AT states, claims 1 to 5 therein were as claims 1 to 5 as maintained by the opposition division, but limited to the gB glycoprotein and Figure 3 (cf. section III above). The embodiments relating to the gH glycoprotein and Figure 5 were claimed separately in claims 6 to 16 with wording identical to the corresponding claims maintained by the opposition division and with the necessary amendments of the dependencies. Claim 17 read as follows:

" A method of preparing HCMV monospecific antiserum, which comprises immunising a host animal with a polypeptide prepared by a process of claim 1 or with a recombinant virus vector of claim 3, and extracting from the host animal antiserum specific to said polypeptide."

The **first auxiliary request** for all non-AT states was identical to the main request, except for the deletion of claim 17.

The claims for AT in these requests were formulated correspondingly as process claims, except for the claims directed to the expression vectors.

VIII. The appellants argued essentially that the claims on file were not entitled to the first priority date because the broad features "in a suitable host organism" and "capable of raising HCMV neutralising antibodies in humans" found no support in the first

priority document (P1). The latter only supported expression in a mammalian cell via a recombinant vaccinia vector of the whole gB polypeptide. Expression in a prokaryotic system such as E.coli or production of fused forms or of fragments of the polypeptide were not disclosed in P1. Nor was a vaccine disclosed therein. In view of this conclusion, document (11) was novelty-destroying for the subject-matter of claims 1 to 5 (main request and first auxiliary request) and of claim 17 (main request). The novelty of the subject-matter of claims 1 and 2 (main request and first auxiliary request) and of claim 17 (main request) was also affected by document (9) and - under Article 54(3) EPC - by document (10). Furthermore, all claims lacked an inventive step, in particular in view of documents (3a + 3b), (5) and (25). As for sufficiency of disclosure, the appellants observed that the immunogenicity of the polypeptide had not been substantiated and the skilled person had no guidance at all as to how to find out whether a given protein met the requirements of the claims.

IX. The respondents replied that the claimed subject-matter was the same invention as disclosed in the first priority document. Consequently, novelty was not at issue as no novelty-destroying document was available before the first priority date. As for inventive step, the claimed subject-matter was to be considered non-obvious in view of the fact that HCMV was an atypical, difficult virus, that the nature of its immunogenic polypeptides was obscure, that the polypeptide HCMV gB had not been identified and that the person skilled in the art, faced with the problem of producing immunogenic HCMV glycoproteins, would not have considered sequencing the entire HCMV genome. As for the objection to sufficiency of disclosure, it was submitted that this should not have been a ground before the Board because no admissible ground for

opposition on the basis of insufficiency was made in the notice of opposition. In any case, the specification described at least one way of identifying and expressing a gene encoding the HCMV gB glycoprotein and provided data on the recognition of the product by the immune system and on the capability of raising neutralising antibodies in rabbits. Under these circumstances, it was not necessary to provide human clinical data.

X. The appellants requested that the decision under appeal be set aside and the European patent be revoked.

The respondents requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or of the first auxiliary request submitted at the oral proceedings on 16 October 1996 or of the second auxiliary request submitted as auxiliary request I with the letter dated 2 December 1994.

Reasons for the Decision

1. The appeal is admissible.

Late-filed documents

2. With regard to the documents filed by the appellants on 13 September 1996 (see section VI above), the Board considers that they do not add anything that could be regarded as important for the purpose of reaching the final decision. As submitted at oral proceedings, the appellants themselves considered these documents merely as supplementary information, not more relevant than other documents already on file. Thus, in exercise of its discretion under Article 114(2) EPC, the Board

disregards them. The English translation of the priority application of document (10) is allowed into the proceedings, as it is important for establishing the priority date for the subject-matter disclosed in the latter document.

Formal admissibility of the amended claims (Article 123(2) and (3) EPC)

3. No formal objections were raised by the appellants against the amended claims of the three requests on file.

4. The Board observes that the amendments do not result in an extension of the protection conferred compared with the claims as granted.

5. The references to Figures 3 and 5 in the claims, which were introduced upon grant of the patent, do not result in subject-matter extending beyond the content of the application as filed, because the said figures correspond exactly to the protein encoded by DNA fragments referred to in the claims as filed. All remaining amendments are of editorial nature and do not result in the presentation of new information when compared with the application as filed.

6. For these reasons, no objections under Article 123(2) and (3) EPC are seen by the Board.

The main request: entitlement to priority (Articles 87 and 88 EPC)

7. The right to priority is governed by Article 87 EPC, which requires that the European patent (application) and the application whose priority is claimed relate to the **same invention**. Article 88(3) EPC further specifies

that, if one or more priorities are claimed in respect of a European patent application, the right of priority shall cover only those elements of the application which are included in the application(s) whose priority is (are) claimed.

Claims 1 to 5

8. The subject-matter of claim 1 is a process which comprises expressing from a recombinant DNA vector in a suitable host organism a polypeptide capable of raising HCMV-neutralising antibodies in humans and which incorporates one or more antigenic determinants from the HCMV glycoprotein gB as represented in Figure 3 for the HCMV strain AD169. Claim 2 relates to the further step of incorporating into a vaccine the polypeptide which is expressed. Subject-matter of claims 3 to 5 is, respectively, a recombinant virus vector capable of infecting a human subject and expressing the said polypeptide in immunogenic form, a vaccine incorporating it and the corresponding expression vector.

9. The first priority document (P1) relates to the production of a vaccine against HCMV using recombinant DNA techniques (see page 1, lines 9 to 11). For this purpose, the said document describes the identification and isolation from the HCMV strain AD169 of a genome fragment encoding the surface glycoprotein gB. The reported DNA and amino acid sequences (see Figure 3) are identical to those of Figure 3 of the patent in suit. It is shown that the incorporation of the said DNA fragment into a recombinant vaccinia vector and the infection therewith of mammalian cells result in the production of an authentic HCMV protein which is the target for neutralising antibody. It is noted that the teaching of the priority document in question, as it would be read by a skilled person, is not limited to

this specific, exemplified embodiment, as maintained by the appellants, but it is of a more general scope as it refers to the expression a protein from the isolated genome fragment by use of conventional genetic engineering techniques in suitable vectors of which vaccinia constitutes an example (see page 2, lines 14 to 27)) and also mentions the possibility of expressing discrete portions of the protein (see page 2, first paragraph and passage starting on page 2, last line and continuing on page 3).

10. In view of the above analysis, the Board is of the opinion that the invention of claims 1 to 5 is the **same** as that disclosed in the first priority document. The lack of actual human clinical data with respect to "the capability of raising HCMV neutralising antibodies in humans" does not necessarily lead to the conclusion that essential elements are missing in the disclosure of the P1 priority document (see, in this respect, eg decisions T 81/87, OJ EPO 1990, 250 and T 296/93, OJ EPO 1995, 627). The patent in suit shows that by proceeding experimentally as taught in the P1 priority document, HCMV-neutralising antibodies are developed in rabbits. This renders plausible that the same effect can be obtained in humans. Thus, in the absence of any challenge to this by the appellants, the Board has no reason to believe that the P1 priority document is deficient in respect of some relevant technical information necessary for reducing to practice the subject-matter of claims 1 to 5. As for the point raised by the appellants that the P1 priority document does not disclose embodiments such as the expression of fusion proteins or the expression in E.coli which are covered by the broad outline of claim 1, the Board observes that none of these embodiments is claimed per se in an individualised manner. The fact that they are embraced by the invention as claimed is irrelevant to

the question of priority if, as in the present case, it is established that this claimed invention is nevertheless the same as that disclosed in the P1 priority document.

11. In conclusion, claims 1 to 5 are considered to be entitled to the priority date of P1, ie 7 March 1986.

Claims 6 to 16

12. Claims 6 to 16 are concerned with methods and means relative to the glycoprotein gH as represented by Figure 5. The validity of the claims in respect of this aspect of the claimed invention has not been challenged by the appellants on the grounds of any prior art, so no issue of priority arises on these claims.

Claim 17

13. Claim 17 concerns a method of preparing HCMV monospecific antiserum, which comprises immunising a host animal with a polypeptide prepared by the process of claim 1 or with a recombinant virus vector of claim 3, and extracting from the host animal antiserum specific to said polypeptide.

14. Although the process of claim 1 and the recombinant virus vector of claim 3 are disclosed in the P1 priority document (see points 8 to 10 above), no explicit mention is found therein of a method of preparing an HCMV monospecific antiserum. Nor can such a method be derived from the said priority document by way of implication. The raising of monospecific antisera against the recombinant gB polypeptide in vaccinated animals is disclosed only in the P2 priority document (see page 7, lines 8 to 10). Thus, claim 17 is considered only to be entitled to the priority date of P2, ie 1 September 1986.

Sufficiency of disclosure (Article 83 EPC)

15. At oral proceedings, the appellant's maintained that, in view of the Board's finding on priority, it was futile to raise objections under Article 83 EPC. Such objections had, however, been raised in the written submissions. In the Board's judgement, the patent specification provides a sufficient disclosure of how to achieve expression in a host organism of a polypeptide which is recognised by HCMV-neutralising monoclonal antibodies and by human HCMV-immune serum and which raises HCMV-neutralising antibodies in rabbits (see pages 5 to 7). As already stated above (see point 10), the absence of actual clinical data on humans is not considered to make it impossible for the skilled person to perform the claimed invention. The data which are available make it plausible that the said polypeptide is capable of raising HCMV-neutralising antibodies also in humans. This is in any case a functional feature the testing of which requires nothing out of the ordinary for the field of medicine and involves only routine trials.

Novelty (Article 54 EPC)

16. In view of the findings on priority, the appellants disputed the novelty of the subject-matter of only claim 17 on the basis of documents (9) or (10). The latter is a conflicting European patent application with priority before the priority date of claim 17. This document - taken together with its priority application (see point 2 above) - discloses the expression in a recombinant system of the protein gp58 encoded by the HindIII-F-fragment of the HCMV genome strain AD169 which corresponds to a protein incorporating one or more antigenic determinants from HCMV glycoprotein gB. The use of the protein which is expressed for diagnostic purposes (see page 5, lines 21

to 26 = page 5 lines 17 to 22 of the English translation of the priority document) and as a vaccine (ibid., page 5, lines 28 to 31 = page 5 lines 24 to 26 of the English translation of the priority document) is also proposed. However, a method of preparing an HCMV monospecific antiserum comprising the steps of immunising a host animal with the protein and extracting from the host animal antiserum specific to said protein is not disclosed in document (10). Nor is such a method described in document (9) which is equally concerned with the identification and expression in E.coli of the HCMV glycoprotein gp58. Thus, in the Board's view, the subject-matter of claim 17 is novel. As for the remaining claims, when account is taken of their priority date as allocated above (see points 8 to 14), none of the documents on file affect their novelty.

Inventive step (Article 56 EPC)

Claims 1 to 5

17. The starting point for the evaluation of inventive step of these claims is represented by the documents which are concerned with the identification, isolation and characterisation of the HCMV envelope proteins from the HCMV strain AD169 in view of their use for raising neutralising antibodies against the HCMV virus. Documents (2), (3a) and (3b) are representative of such art. Of these documents, in particular document (3b) showed that at least three polypeptides were targets for virus-neutralising antibody, these being a single protein p86 and two co-immunoprecitipating proteins p130/55. As reported therein, immunisation with these polypeptides resulted in the formation of neutralising

antibody in guinea pigs. In the case of p130/55, this was complement-dependent. Document (3b) concluded that these viral polypeptides could be major immunologic determinants on the viral envelope.

18. In the light of said prior art, the technical problem to be solved is the provision of an alternative process for the production of sufficient amounts of an immunogenic HCMV envelope protein to be used as a vaccine.

19. The solution proposed by the claims at issue is a recombinant DNA method and means for the expression in a suitable host of a DNA sequence encoding one or more antigenic determinants from the HCMV glycoprotein gB as represented in Figure 3. The examples in the patent in suit show that the said method and means indeed allow the production of a polypeptide capable of raising HCMV-neutralising antibodies. The Board is thus satisfied that the above-stated technical problem is solved by the claimed invention. At issue here is whether at the priority date it was obvious to a skilled person to arrive at something falling within the terms of the claims from the guidance available in the prior art.

20. When faced with the above-stated technical problem, the skilled person would have readily considered the application of one of the known recombinant DNA techniques. For this, however, the skilled person would have needed to know first of all what to look for. Thereby, he or she would have immediately realised that the prior art did not point directly to a single envelope protein responsible for neutralising activity, but to a number of proteins (see documents (2), (3a) and (3b)) none of which was characterised in terms of either the amino acid sequence or the localisation of the corresponding gene on the HCMV genome. In spite of

the availability of neutralising monoclonal antibodies reacting with HCMV-glycoproteins, the nature of these glycoproteins was still poorly defined (see as an expert opinion document (9), in particular page 461). As for the HCMV genome, which was known to be quite large (240-kilobase-pair), the only information available to the skilled person were the physical maps for the HindIII, BglII and XbaI restriction endonucleases published in document (6) and the description in document (25) of the mapping on the HCMV genome of a HCMV protein family - referred to as the ICP36 family - by use of λgt11 and monoclonal antibodies. The latter family was non-structural and consisted of DNA-binding phosphoproteins possibly involved in the regulation of viral growth and thus different from the multiple glycoprotein of the viral envelope referred to in documents (2), (3a) and (3b).

21. In the Board's judgement, the fragmentary and incomplete information available from the prior art as depicted above, would not have provided the skilled person with sufficient guidance to the identification and isolation from the HCMV genome of a DNA fragment located at the HindIII F/D boundary capable, upon insertion in a recombinant DNA vector, of causing in a suitable host the expression of a polypeptide capable of raising HCMV-neutralising antibodies. Only with hindsight it is now possible to relate the DNA fragment which was identified and isolated in the patent in suit to one of the many glycoproteins known from the art and to trace back the way leading to its localisation within the HCMV genome. In assessing this question, the Board was greatly assisted by the evidence of Professor Lenore Pereira, given at the oral proceedings. Professor Pereira was a leading expert in this field at the time, having indeed more knowledge and skill than the Board assumes for the purpose of its consideration of inventive step the notional skilled person would

have. Yet her evidence showed that despite this knowledge and skill, and despite her attempting all the routes that obviously suggested themselves for solving the problem, she was unable to come up with the solution now claimed. In these circumstances, the subject-matter of claims 1 to 5 is considered as non-obvious for the skilled person.

Claim 17

22. The starting point for the evaluation of inventive step of this claim is represented by document (9) - published before the P2 priority date - which document dealt with the identification and expression in E.coli of the HCMV glycoprotein gp58. The document reported that this glycoprotein - called gA - was encoded by a DNA sequence in the right end of the HindIII-F-fragment of the HCMV genome of strain AD169. This corresponds to the HindIII F/D boundary of the patent in suit. Thus, the isolated DNA region overlaps with or falls within that encoding glycoprotein gB as represented by Figure 3 of the patent in suit. Document (9) showed that E.coli cells transformed with a recombinant vector containing a DNA insert from the said region produced a single fusion protein with an HCMV glycoprotein gA part which fusion protein was recognised by a monospecific antiserum raised against the gp58 protein isolated from HCMV.

23. In the light of the said prior art document, the technical problem underlying claim 17 is the provision of a recombinant DNA method for producing a monospecific HCMV antiserum.

24. The solution proposed by claim 17 is a method based on the production by recombinant DNA techniques of a polypeptide capable of raising HCMV-neutralising antibodies which incorporates one or more antigenic

determinants from the HCMV glycoprotein gB as represented in Figure 3, the DNA encoding said polypeptide being located at HindIII F/D boundary in the HCMV genome.

25. When faced with the above-stated technical problem, the skilled person, starting from the teaching of document (9), would have readily pursued the experimental line laid down therein and tried to further complete and improve the work described. Thus, the skilled person would have focused his or her attention on the expression on the same or an alternative recombinant system of an immunologically active form of the polypeptide encoded by the mapped DNA sequence in the right end of the HindIII-F-fragment of the HCMV genome of strain AD169. As the expression of at least part thereof had already been achieved in document (9), where it had been shown that a fused expression product was recognised by a monospecific antiserum raised against the gp58 protein from HCMV, the skilled person would have expected this to be readily feasible without any particular difficulties by the mere application of standard techniques and routine trials. Accordingly, also the subsequent use of the expressed product for making of an HCMV monospecific antiserum would have been within the reach of the skilled person, especially in consideration of the fact that a monospecific antiserum against the surface glycoprotein gp58 isolated from the virus had been prepared. Thus, in the Board's opinion, the skilled person, on the basis of the available prior art and common general knowledge, would have arrived at something within the terms of claim 17 in a straightforward manner, ie without the application of inventive skill or undue experimentation. The observation by the respondents that the methods used in document (9) were unsuitable for the production of an active vaccine cannot affect the Board's conclusion

because - as it manifest also from the conclusions drawn by the Board in respect of the issues of entitlement to priority, sufficiency of disclosure and inventive step of the subject-matter of claims 1 to 5 - the difficulties faced by the skilled person in the present case were not linked to the technicalities of the expression of a polypeptide suitable as a vaccine, but to the fragmentary and incomplete information available from the prior art. However, once the target envelope protein and the localisation of the corresponding gene on the HCMV genome were known, as here for the purpose of claim 17, from document (9), the skilled person had merely to carry out routine work in order to solve the stated underlying technical problem. Under these circumstances, an inventive step is to be ruled out for the subject-matter of claim 17. Consequently, the main request, of which this claim is part, is refused as claim 17 does not meet the requirements of Article 56 EPC.

The first auxiliary request

26. This request differs from the main request only in that it does not contain claim 17. As for the remaining claims, the subject-matter of claims 1 to 5 has already been acknowledged as inventive (see points 17 to 21 above) and the subject-matter of claims 6 to 16 relating to the glycoprotein gH as represented by Figure 5 has not been challenged in any way by the appellants. For these latter claims, no specific prior art exists, the identification and characterisation of the gH gene being a merit of the patent in suit. Thus, the subject-matter of all claims of this request involves an inventive step and the request is allowable. The Board sees no need for the description being adapted.

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 claims 1 to 16 of the first auxiliary request in the two versions for non-AT states and for AT submitted at oral proceedings on 16 October 1996.

The Registrar: The Chairperson:

L. McGarry U. M. Kinkeldey