

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

**Datasheet for the decision
of 31 March 2011**

Case Number: T 1456/06 - 3.3.08

Application Number: 97307757.1

Publication Number: 0841396

IPC: C12N 15/54

Language of the proceedings: EN

Title of invention:

Human telomerase catalytic subunit

Applicants:

Geron Corporation
The Regents of the University of Colorado

Opponent:

GemVex AS

Headword:

Telomerase/GERON

Relevant legal provisions:

EPC Art. 83, 123(2)(3)
EPC R. 99(1)(a)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Correction of notice of appeal (yes)"
"Admissibility of the appeals (yes)"
"Main request and auxiliary request 1 - added matter (yes)"
"Auxiliary requests 2 to 4 - sufficiency of disclosure (no)"
"Auxiliary request 5 - requirements of the EPC met (yes)"

Decisions cited:

T 0097/98, T 0579/01, T 0903/05

Catchword:

-



Case Number: T 1456/06 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 31 March 2011

Appellants I:
(Applicant)

Geron Corporation
230 Constitution Drive
Menlo Park
CA 94025 (US)

(Applicant)

The Regents of the University of Colorado
1800 Great Street, 8th Floor
Denver, CO 80203 (US)

Representative:

Broughton, Jon
avidity IP
Merlin House
Falconry Court
Baker's Lane
Epping
Essex CM16 5DQ (GB)

Appellant II:
(Opponent)

GemVex AS
Noreveien 7
NO-0379 Oslo (NO)

Representative:

Arends, William Gerrit
Marks & Clerk LLP
90 Long Acre
London WC2E 9RA (GB)

Decision under appeal:

Interlocutory decision of the Opposition
Division of the European Patent Office posted
19 July 2006 concerning maintenance of European
patent No. 0841396 in amended form.

Composition of the Board:

Chairman: R. Moufang
Members: M. R. Vega Laso
P. Julià

Summary of Facts and Submissions

I. European patent No. 0 841 396 with the title "Human telomerase catalytic subunit" is based on European patent application No. 97307757.1 (in the following "the application as filed"). The patent was granted with 47 claims.

II. Claims 1, 44, 46 and 47 as granted read:

"1. A polynucleotide comprising a sequence encoding a polypeptide capable of exhibiting a telomerase catalytic activity when associated with a telomerase RNA and which is:

- (a) a polynucleotide having the sequence of the insert of plasmid ATCC 209016; or
- (b) a polynucleotide which hybridizes to (a) under stringent conditions; or
- (c) a polynucleotide which hybridizes to SEQ ID NO 3 or SEQ ID NO 8 under stringent conditions; or
- (d) a polynucleotide sequence which is degenerate as a result of the genetic code to the sequences defined in (a) or (b).

44. The use of a polypeptide obtainable by expressing the polynucleotide of claim 1 in a vector of claim 5 or an immunogenic fragment thereof in the preparation of a vaccine capable of eliciting an immune response.

46. An immunogenic peptide of human telomerase protein, said peptide comprising at least 8, optionally at least 10, amino acids of a human telomerase protein encoded by the polynucleotide of claim 1 for use in medicine.

47. The use of an immunogenic peptide of human telomerase protein, said peptide comprising at least 5, optionally at least 8 or at least 10, amino acids of a human telomerase protein encoded by the polynucleotide of claim 1 for the manufacture of a medicament for the treatment of a condition mediated by cells expressing high levels of telomerase."

III. An opposition to the grant of the patent was filed. The opposition was based on the grounds for opposition mentioned in Article 100(a), (b) and (c) EPC 1973, in particular that the subject-matter of claims 44, 46 and 47 as granted extended beyond the content of the application as filed and also lacked an inventive step within the meaning of Article 56 EPC 1973, and that the invention as claimed in claims 1, 44, 46 and 47 was not sufficiently disclosed in the patent.

IV. By an interlocutory decision under Article 102(3) and 106(3) EPC 1973 posted on 19 July 2006, the opposition division decided that claims 46 and 47 of the set of claims filed at the oral proceedings as main request offended against Article 123(2) EPC 1973, and that claim 46 according to the first auxiliary request filed also at the oral proceedings did not conform to Article 123(3) EPC 1973. The invention claimed in claims 44 and 46 according to the second auxiliary request filed at the oral proceedings was regarded as not having been sufficiently disclosed, contrary to Article 83 EPC 1973. However, the opposition division found that, having regard to the amendments introduced into the set of claims according to the third auxiliary

- request filed at the oral proceedings, the patent could be maintained on that basis.
- V. Both the patent proprietors (appellants I) and the opponent (appellant II) lodged an appeal against the interlocutory decision of the opposition division (the omission of the second co-proprietor in the notice of appeal was later corrected, see paragraphs VII, XVIII, XIX and 1-3 below). Together with their statement of grounds of appeal, appellants I submitted additional evidence and seven sets of amended claims as main request and auxiliary requests I to VI, respectively. As a subsidiary request, both parties requested oral proceedings.
- VI. Each party was given the opportunity to reply to the grounds of appeal of the other party. Together with their reply, appellants I submitted three declarations and copies of thirteen scientific publications cited in the declarations. Further documentary evidence was filed by appellant II together with its reply.
- VII. The parties were summoned to oral proceedings. In a communication under Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) attached to the summons to oral proceedings, the board observed that the appeal had been filed in the name of only one of the two co-proprietors of the patent in suit. The board also provided comments on the amendments introduced into the sets of claims filed with the statement of grounds of appeal, as well as on some of the issues discussed in the decision under appeal.

VIII. By letter dated 21 February 2011 in response to the board's communication, appellants I filed six sets of amended claims as, respectively, main request and auxiliary requests 1 to 5, which replaced their previous requests.

IX. The set of claims according to the **main request** differs from the claims as granted in that claims 46 and 47 read as follows:

"46. An immunogenic peptide of human telomerase protein for use in medicine, said peptide comprising at least 8 amino acids of a human telomerase protein encoded by the polynucleotide of claim 1, said peptide capable of inducing specific antibodies against human telomerase protein.

47. The use of an immunogenic peptide of human telomerase protein, comprising at least 8 amino acids of a human telomerase protein encoded by the polynucleotide of claim 1 for the manufacture of a medicament for the treatment of cancer, by eliciting a Class I MHC restricted cytotoxic lymphocyte response against cells expressing high levels of telomerase."

X. The claims according to **auxiliary request 1** differ from those of the main request in that claim 46 has been deleted, and claim 47 renumbered as claim 46.

XI. The claims according to **auxiliary request 2** differ from those of auxiliary request 1 in that the wording "*..., comprising at least 8 amino acids of a human telomerase protein ...*" has been deleted from claim 46.

- XII. The set of claims according to **auxiliary request 3** differs from that of the main request in that claim 47 has been deleted, and in the set of claims according to **auxiliary request 4**, also claim 46 has been deleted.
- XIII. Finally, claims 1 to 44 according to **auxiliary request 5** differ from the set of claims of the main request in that claims 44, 46 and 47 have been deleted and claim 45 renumbered as claim 44.
- XIV. In reply to the board's communication, appellant II filed observations and additional documentary evidence.
- XV. Appellants I submitted further comments on the issue of admissibility of their appeal.
- XVI. Oral proceedings were held on 31 March 2011.
- XVII. The following documents are referred to in the present decision:
- (23): Declaration of Prof. David Wraith, dated 9 April 2006;
- (27): E. Celis et al., 1995, Seminars in Cancer Biology, Vol. 6, pages 329 to 356;
- (55): Second declaration of Prof. David Wraith, dated 27 November 2006;
- (69): L. S. Klavinskis et al., 1990, Virology, vol. 178, pages 393 to 400;

DW1: Immunobiology, 1996, 2nd edition,
ed. Ch.A. Janeway, Jr. and P. Travers;

DW2: H.-G. Rammensee et al., 1995, Immunogenetics,
Vol. 41, pages 178 to 228;

Declaration of Dr Michael Dahm, dated 18 April 2007;

Declaration of Dr Howard Grey, dated 16 April 2007.

XVIII. The submissions made by the appellants I, as far as they are relevant to this decision, may be summarized as follows:

Request for correction and admissibility of the appeals

It had been always the intention of both Geron Corporation and the Regents of the University of Colorado to become appellants. Since there was an agreement between the co-proprietors that Geron Corporation was entrusted with taking all necessary procedural steps, the notice of appeal was submitted by Geron Corporation. However, the term "patentee" in the notice was meant to include both co-proprietors. There was no intention that the Regents of the University of Colorado should be omitted. The omission of the name of the second co-proprietor was a clerical error.

The corrected notice of appeal and statement of grounds of appeal fulfilled the requirements in Rule 99(1)(a) EPC.

Main request - Article 123(2) EPC - Claims 46 and 47

The passage at page 72 of the application as filed clearly related to medical research and provided basis for immunogenic telomerase peptides of at least 8 amino acids for use in medicine. While the passage on page 99, lines 19 to 22 relating to telomerase peptides capable of eliciting an immune response in a patient, did not explicitly disclose the minimum length of the telomerase peptides recited in claims 46 and 47, document (55), a declaration by Prof. Wraith based upon his own knowledge, was evidence for the fact that, at least as far back as 1995, peptides capable of eliciting a class I MHC restricted response would have at least 8 amino acids.

Auxiliary request 2

Article 123(3) EPC

Since peptides of less than 8 amino acids were not suitable for eliciting a class I MHC restricted response, the correct and sensible interpretation of amended claim 46 was that the peptide being used was at least 8 amino acids long. It would go contrary to the skilled person's knowledge and reason to interpret the claim as covering peptides that are shorter than 8 amino acids in length.

Article 83 EPC

Claim 1

Claim 1, which was directed to the sequence of the gene encoding the protein component of human telomerase, reflected the contribution of the invention to the art.

The errors in the sequence of SEQ ID NO 3 recited in the claim were readily apparent to the skilled person and he/she would look for supplementary information from the rest of the specification. Both Figures 68 and 16 of the specification would lead the skilled person immediately to the correct sequence.

The claims must be interpreted by a mind willing to understand. The insert of the plasmid as recited in claim 1 part (a) was, of course, double stranded in any event, and accordingly, the polynucleotides of part (b) could be of either strand, either sense or antisense. Naturally, the skilled person would have no difficulty in choosing a sense strand polynucleotide in order to satisfy the functional requirements of claim 1. A similar, sensible approach would be applied to part (c) of claim 1.

Claim 44

It was quite normal, in addition to claiming a new and inventive product, to claim uses of that product that did not, in themselves, purport to have any "extra" inventive step above the product itself. For claims directed to routine methods of preparation of medicaments and vaccines, in order to meet the requirements of Article 83 EPC it should only be necessary to demonstrate, firstly, that on the basis of the content of the patent and the common general knowledge at the priority date, it was plausible that the invention would work, and secondly that there was no serious doubts substantiated by verifiable facts that the invention, in fact, works. A claim directed to a pharmaceutical use should be accepted under

Article 83 EPC if, at the time of filing, there was, first, a clear and established relationship between the physiological activity of the product and a disease, and, second, the skilled person recognized the suitability of the product to be manufactured for the claimed therapeutic application. While the second point was normally demonstrated by experiments, there was no reason why this evidence should not be based upon the prior art or common general knowledge. In the present case, there was a sound link between the physiological effect on the target and the indication in question, based on the state of the art. Since telomerase was recognized as having the characteristics of a tumor antigen, it was plausible that, within the protein, there were suitable immunogenic peptides that would be effective as a cancer vaccine.

The process of selection of a candidate peptide for a vaccine was certainly no more burdensome than pharmaceutical candidate selection. It was irrelevant whether or not the specification provided instructions sufficient to allow the skilled person to provide a vaccine, because he/she would possess the required scientific understanding and knowledge. A person skilled in the art would know how to go about selecting candidate peptides for trial, and how to assay clinical effectiveness. There was no evidence that this was anything other than a routine (albeit time-consuming) process. Naturally, some selected candidate peptides might not become clinical successes, but this would not be a more significant factor than in any standard pharmaceutical case. The amount of burden involved in a trial and error process was not necessarily altered merely because there were a number of variables that

might affect the outcome. Only if there was evidence that the number of variables had a material negative effect on the likelihood of success, such that the process moved from true "trial and error" to one of inventive investigation, or such that the skilled person would find the prospects of success very low, there was likely to be an undue burden.

Auxiliary request 5

The claims of the auxiliary request 5 were identical to the claims upheld by the opposition division. These claims fulfilled all requirements of the EPC.

XIX. The submissions by appellant II were as follows:

Request for correction and admissibility of the appeals

Since both the notice of appeal and the statement of grounds of appeal referred only to the "patentee" in the singular, it was not self-evident that the omission of reference to The Regents of the University of Colorado was an unintentional oversight. Moreover, the request for correction of the appeal did not meet the requirements for correcting the deficiency because it was not supported by evidence that the "correction does not reflect a later change of mind as to whom the appellant should be", as stated in decision T 97/98 (OJ EPO 2002, 183).

Main request - Article 123(2) EPC - Claims 46 and 47

The opposition division was correct in concluding that the passage on page 72 of the application as filed did

not provide basis for claim 46 because it referred to the preparation of antibodies to be used as laboratory tools and not for therapeutic use. The combination of that passage which related to a non-therapeutic context with the meaning of claim 46 as a first medical use claim involved taking the passage out of its non-therapeutic context and putting it into a therapeutic context.

The passage on page 99 of the application as filed was not an appropriate basis for claim 47 because that passage did not refer to the treatment of cancer. The term "malignant cells" was not synonymous with "cancer". Moreover, a person skilled in the art would not understand the sentence in lines 25 to 27 of page 99 as referring to the use of peptides to generate a class I MHC restricted CTL response, but rather to the delivery of plasmid vectors, which could then result in expression of telomerase proteins within a cell and presentation via a class I MHC molecule.

Auxiliary request 2

Article 123(3) EPC

As shown in documents (69) and (73), peptides shorter than eight amino acids (namely of seven amino acids in length) did bind class I MHC molecules. Thus, the opposition division's reasoning in the decision under appeal was erroneous.

Article 83 EPC

Claim 1

The polynucleotides of claim 1 were not sufficiently disclosed. Contrary to the opposition division's view, a person skilled in the art would not be able to understand what was intended by the sequence shown in Figure 18 (SEQ ID NO:3). Since there were substantial differences between the sequences of Figures 16 and 18, a skilled person would not have regarded Figure 16 as a suitable source of corrections for the errors in Figure 18.

Polynucleotides which hybridized to the insert of plasmid ATCC 209016 or to the SEQ ID NO 3 or SEQ ID NO 8 would clearly have a complementary sequence, i.e. they would be the "antisense" sequence rather than the "sense" sequence. However, an "antisense" sequence could not encode a polypeptide capable of exhibiting a telomerase catalytic activity, as required by claim 1.

Claim 44

It was not necessarily plausible that a protein that was a tumour antigen would contain an immunogenic peptide that could be used as a cancer vaccine. The telomerase peptides disclosed in the application were reported only for the purpose of production of anti-hTERT antibodies. The specification did not contain data confirming that any of those peptides functioned as a vaccine.

XX. Appellants I (patent proprietors) requested to correct the notice of appeal and the statement of grounds of

appeal in that the name of the co-proprietor - The Regents of the University of Colorado - is indicated as co-appellant. Furthermore, the appellants I (patent proprietors) requested to set aside the decision under appeal and to maintain the patent in amended form on the basis of the main request or, in the alternative, of auxiliary requests 1 to 4, all requests filed with letter of 21st February 2011, or - as auxiliary request 5 - to dismiss the appeal of appellant II.

XXI. Appellant II (opponent) requested to set aside the decision under appeal and to revoke the patent.

Reasons for the Decision

Request for correction of the notice of appeal and the statement of grounds of appeal

1. In view of the arguments and evidence on file, the board has no reason to doubt that the true intention of appellants I was to file the appeal in the name of both Geron Corporation and The Regents of the University of Colorado, and that the erroneous omission of the name of the latter as co-appellant in the notice of appeal and the statement of grounds of appeal was not intentional. Since it is immediately evident that only the co-proprietor, i.e. The Regents of the University of Colorado, could have been intended as co-appellant, it is obvious what the correction of the error should be.
2. For these reasons, appellants I's request for correction of the notice of appeal and the statement of

grounds of appeal to the effect that the name of the co-proprietor - The Regents of the University of Colorado - be indicated as co-appellant is granted.

Admissibility of the appeals

3. According to Rule 64(a) EPC 1973, which corresponds to present Rule 99(1)(a) EPC, the notice of appeal shall contain the name and address of the appellant(s). In the present case, the notice of appeal and the statement of grounds of appeal filed by Geron Corporation did not include the name of its co-appellant. However, this deficiency has been remedied in good time by requesting a correction of both submissions (see paragraphs 1 and 2 above). Since the requirement of Rule 64(a) EPC 1973/Rule 99(1)(a) EPC is considered to be fulfilled, the board holds the appeal lodged by appellants I to be admissible.
4. No objections concerning the admissibility of the appeal of appellant II have been raised by the other party, and the board does not see any reason to raise any of its own motion.
5. Both appeals are considered to be admissible.

Main request - Article 123(2) EPC

Claims 46 and 47

6. Amended claim 46 according to the present main request (see paragraph IX above) differs from the corresponding claim of the main request on which the decision under appeal was based, in that the feature "*for use in*

medicine" is now included in the preamble of the claim, a new feature ("*..., said peptide capable of inducing specific antibodies against human telomerase protein*") has been introduced, and the wording "*..., optionally at least 10 [amino acids], ...*" has been deleted.

7. In the decision under appeal, the opposition division found in respect of claim 46 of the main request then on file - which was identical to claim 46 as granted (see paragraph II above) - that the claimed subject-matter could not be derived, directly and unambiguously, from the application as filed. Immunogenic peptides of human telomerase protein comprising "*... at least 8 [...] amino acids of a human telomerase protein ...*" were considered to be disclosed in the application as filed only in connection with the generation of antibodies, but not with regard to a use in medicine, as it was specified in claim 46. In the view of the opposition division, the subject-matter of claim 46 could be regarded as a combination of two separate embodiments of the invention, which a person skilled in the art reading the application as filed had no reason to combine. The opposition division decided to disregard the documentary evidence submitted by the patent proprietors in support of their line of argument that the peptide length specified in claim 46 was derivable from the common general knowledge of a skilled person at the filing date because, first, the documents in question had been published after the relevant date and, second, the feature at issue was not directly derivable from the documents.

8. In appeal proceedings, appellants I contested the findings of the opposition division arguing along two

lines. On the one hand, they contended that the medical use of immunogenic telomerase peptides comprising at least 8 amino acids was directly and unambiguously derivable from various passages of the application as filed. On the other hand, they argued that it was part of the common general knowledge at the priority date that 8 amino acids was the minimum length necessary in order to induce a Class I MHC cytotoxic response. As concerned the meaning of feature "*for use in medicine*", appellants I accepted the opposition division's interpretation of claim 46 as being directed to a "first medical use", and acknowledged that, in spite of the feature in question being at a different position within claim 46 of the present main request, its meaning had not changed.

9. In view of the evidence on file, the board is not persuaded that a person skilled in the art at the relevant date could derive, directly and unambiguously, a medical use of immunogenic peptides of the human telomerase protein **comprising at least 8 amino acids** as defined in claim 46, either from the application as filed or from his/her common general knowledge.
10. Like the opposition division, the board interprets the feature "*for use in medicine*" broadly. Hence, claim 46 is construed as including **any** medical use of telomerase peptides as defined in the claim, in particular the treatment of disease conditions in human patients. The board notices that, even though the additional feature introduced into the amended claim 46 requires the peptide to be capable - under conditions not specified in the claim - of eliciting specific antibodies against the human telomerase protein, this feature imposes, in

the board's view, no further limitation on the claimed **immunogenic** peptides, and in particular no limitation with respect to possible medical uses.

11. The passages of the application as filed indicated by appellants I cannot be accepted as adequate basis for the subject-matter of claim 46. While it is true that telomerase peptides having an amino acid sequence consisting of at least 8 amino acids are disclosed in the passage on page 72, lines 12 to 14 of the application as filed, the disclosure in this passage relates to peptides which are used as antigens with the aim of producing antibodies specific for human telomerase protein in laboratory animals (see first full paragraph on page 72 of the application as filed). The same applies to the disclosure in Example 8 (see page 257ff. of the application as filed), which describes the production of anti-hTERT antibodies in rabbits using as antigen four specific telomerase peptides with a length between 23 and 27 amino acids coupled to a protein carrier. Even if this use of the telomerase peptides were to be regarded as a "use in medicine" - as appellants I argued -, the disclosure of this specific use cannot be accepted as basis for a claim which is directed to immunogenic peptides for any kind of medical use.

12. The passage on page 99, lines 19 to 22 of the application as filed concerns the use of immunogenic telomerase peptides to elicit an immune response in a patient, i.e. to act as a vaccine. This can be regarded, in fact, as a medical use. However, as appellants I admitted, no information is explicitly given in this passage with respect to the minimum length of suitable

immunogenic peptides. Since there is also no reference whatsoever to the passage on page 72 which may suggest a link between both passages, a person skilled in the art reading the application as filed would not necessarily consider combining the two passages into one teaching. Thus, the board cannot acknowledge a basis in the application as filed for the subject-matter of claim 46.

13. Nor can the board accept appellants I's argument that a person skilled in the art at the filing date would have been able to derive from his/her general knowledge the specific information on the minimum length of required immunogenic peptides of human telomerase protein.

14. In appeal proceedings, appellants I relied on document (55) in connection with documents DW1 and DW2 as evidence for the common general knowledge at the relevant date. The relevant passages in document (55) are:

*"Peptides that bind MHC class one molecules are usually **eight to 10 amino acids long**" (page 2, second paragraph of the quotation from DW1; underline added by the board)*

"The human MHC class I binding peptides identified at this time were preferably nine or 10 amino acid in length" (page 3, lines 1 and 2; underline added by the board)

15. The wording "usually" and "preferably" used in these passages appears to indicate that the length of the peptides must not be necessarily eight, nine or ten amino acids, but could be also less. This is confirmed

by the passage bridging pages 395 and 396 and Table 2 of document (69), in which a peptide with seven amino acids is described as minimal sequence for *in vitro* CTL response to LCMV (lymphocytic choriomeningitis virus). The fact that this peptide was not subsequently tested to determine the minimum sequences required to afford protection from LCMV infection does not, contrary to appellants I's view, question the findings *in vitro*. In this respect, it should be noted that document (55) - the counter-evidence provided by appellants I for a minimum length of 8 amino acids - refers exclusively to peptide **binding** to Class I MHC molecules.

16. For these reasons, the board judges that claim 46 of the present main request - in spite of the introduced amendments - still suffers from the same deficiencies under Article 123(2) EPC found by the opposition division to be prejudicial to the maintenance of the patent on the basis of the main request then on file (see paragraph 8 above).

17. The adverse findings on claim 46 with respect to the lack of basis for peptides comprising at least 8 amino acids of the human telomerase protein in the passage on page 99 of the application as filed (see paragraphs 12 to 15 above) apply also - *mutatis mutandis* - to claim 47 which is drafted in the form of a "second medical use" claim and relates to the treatment of cancer by eliciting a Class I MHC restricted cytotoxic lymphocyte response against cells expressing high levels of telomerase.

18. Hence, since the set of claims according to the main request offend against Article 123(2) EPC, the patent cannot be maintained on this basis.

Auxiliary request 1 - Article 123(2) EPC

19. Claim 46 of auxiliary request 1 is identical in wording to claim 47 of the main request. Thus, the reasons given above in respect of the latter claim in connection with Article 123(2) EPC apply - *mutatis mutandis* - also to claim 46 of this request.

20. Consequently, Article 123(2) EPC prejudices the maintenance of the patent on the basis of the set of claims according to auxiliary request 1.

Auxiliary request 2

Article 123(3) EPC

21. Claim 46 of auxiliary request 2 (see paragraph XI above) is identical to claim 47 of auxiliary request 1 in opposition proceedings. In the decision under appeal, the opposition division held that, although the feature "..., comprising at least 8 amino acids of a human telomerase protein ..." had been deleted in the amended claim 47, the scope of the claim had *de facto* remained the same (see paragraph 2.2.14 of the decision under appeal). Consequently, the opposition division found that Article 123(3) EPC was not contravened. This finding has been contested by appellant II.

22. Albeit for different reasons, the board reaches the same conclusion as the opposition division.

23. Article 123(3) EPC rules that a European patent may not be amended in such a way as to extend the protection it confers. According to the established jurisprudence of the Boards of Appeal, the legal notion of "protection conferred" in Article 123(3) EPC does not necessarily refer to the scope of protection of each single claim as granted, but rather to the totality of the protection established by the claims as granted as a whole. Thus, in order to assess whether or not an amendment introduced to the claims as granted offends against Article 123(3) EPC, the question to be decided is whether or not, in comparison to the claims as granted, the protection conferred by **the totality** of the claims has been extended (see decision T 579/01 of 30 June 2004).
24. In the present case, the board is persuaded that, although the deletion of the feature "*..., comprising at least 8 amino acids of a human telomerase protein ...*" may possibly result in a different scope of amended claim 46 compared to that of claim 47 as granted from which the amended claim is derived, the protection conferred by the totality of the claims as granted has not been extended by the amendment because the subject-matter of amended claim 46 is within the scope of protection conferred by the patent as granted.
25. Amended claim 46 is directed to the use of an immunogenic peptide of the human telomerase according to the invention for the manufacture of a medicament "*... for the treatment of cancer by eliciting a Class I MHC restricted cytotoxic lymphocyte response against cells expressing high levels of telomerase*". In the

board's judgement, a medicament which elicits a lymphocyte response is nothing else than a vaccine. Thus, in other words, amended claim 46 is directed to the use of an immunogenic peptide of the human telomerase for the manufacture of a vaccine, in particular a therapeutic vaccine ("*... for the treatment of cancer ...*") which elicits a specific type of immune response, namely a Class I MHC restricted cytotoxic lymphocyte response.

26. Claim 44 as granted was directed to the use of an immunogenic fragment of the human telomerase according to the invention in the preparation of a vaccine capable of eliciting an immune response. Claim 44 as granted was not restricted to the treatment of a particular disease or to a specific type of immune response, as it is the case in amended claim 46. Thus, the more limited subject-matter of amended claim 46 falls within the scope of claim 44 as granted. The slight difference in wording between the two claims (amended claim 46 reads "*... for the manufacture of...*" instead of "*... in the preparation of ...*" as in claim 44 as granted) does not appear to have any significance with regard to the claim scope. If anything, the wording "*... in the preparation of ...*" in claim 44 as granted could be considered to have a broader meaning.
27. For these reasons, appellant II's argument that, as a result of the amendment introduced into claim 46, the protection conferred by the patent has been extended, cannot be accepted.

Article 83 EPC

Claim 1

28. In the decision under appeal, the opposition division found - in connection with the second auxiliary request then on file - that the invention as claimed in claim 1 was sufficiently disclosed in both the application as filed and the patent as granted. Claim 1 of the present auxiliary request 2 is identical to the claim on which the opposition division decided, and also identical to claim 1 as granted.
29. Appellant II contested the opposition division's finding arguing along two lines (see paragraph XIX above). Neither line of argument can be accepted.
30. The objection under Article 83 EPC raised by appellant II against alternatives (b) and (c) in claim 1 is, in the board's view, a clarity issue arising from misfortune in claim drafting rather than an actual problem of insufficiency of disclosure. While it is true that polynucleotides which hybridize to a polynucleotide encoding the telomerase polypeptide cannot encode a polypeptide with telomerase activity, as apparently required by claim 1, the board is persuaded that a person skilled in the art reading claim 1 with a mind willing to understand would realize immediately that a polynucleotide hybridising to a second polynucleotide must have (at least in part) the complementary sequence and, therefore, cannot encode the same polypeptide. Since lack of clarity is not a ground of opposition, and the clarity deficiency to

which appellant II pointed does not arise from an amendment to claim 1, but was already present in the claim as granted, the objection must fail.

31. As regards appellant II's objection concerning individual errors or missing symbols in the sequences of Figures 18 and 68, the opposition division pointed in its decision to Figure 16 of the application as filed as the correct sequence. This has not been disputed by appellant II which, in appeal proceedings, based its line of argument on speculative assumptions of possible deletions rather on verifiable facts. Thus, also this objection must fail.

32. Consequently, the invention according to claim 1 is considered to fulfil the requirement of Article 83 EPC.

Claim 44

33. With regard to the question whether or not a person skilled in the art can find in the application as filed - supplemented with the common general knowledge at the relevant date - sufficient technical information for carrying out the invention as claimed in claim 44 without any inventive effort and undue burden of experimentation, the opposition division established that, except for providing the nucleotide and polypeptide sequence of, respectively, the human telomerase gene and protein, the specification contained no specific instructions how a vaccine capable of eliciting an immune response could be produced, nor any data confirming that any of the peptides described in Example 6 or 8 of the application as filed would, as a component of a vaccine, elicit an

immune response. Thus, in the view of the opposition division, a person skilled in the art was *"not put in a position to be able to arrive at the claimed vaccine, indicating that claim 44 is insufficiently disclosed"* (see paragraph 2.3.4 of the decision under appeal).

34. The board observes that the application as filed contains, in fact, no technical information concerning vaccines, but only a few rather general statements about possible vaccines containing immunogenic peptides with a telomerase sequence for eliciting an immune response against cells expressing high levels of telomerase, e.g. malignant cells (see passage from page 99, lines 18 to 29 of the application as filed). In Example 6 ("Design and construction of vectors for expression of hTERT proteins and oligonucleotides") some telomerase fragments are described, and in Example 8 ("Production of anti-hTERT antibodies") four peptides used as antigens for producing anti-telomerase antibodies in rabbits are disclosed.
35. Appellants I argued that a person skilled in the art could have chosen any of the peptides disclosed in the application as a candidate for the manufacture of a vaccine. However, the board has not been able to find any suggestion to this effect in the application. Moreover, there is no indication in the application as filed, let alone evidence whatsoever which makes plausible that any of these particular peptides may elicit an immune response in humans and be suitable as a component of a vaccine.
36. It was also argued by appellants I that a person skilled in the art could, applying methods well-known

in the art, identify immunogenic peptides suitable for the production of a vaccine. In their view, no new methodology would be necessary, but only routine work based on trial and error. As evidence in support of this argument, documents (27) and (23) and the declarations by Dahm and Grey (see paragraph XVII above) were cited.

37. The board disagrees with this view. It is apparent from document (27) that the development of peptide-based vaccines to treat cancer - the sole specific type of vaccine mentioned in the application as filed - is not only extremely laborious, but also fraught with uncertainties. Specifically, self-tolerance and autoimmune potential are mentioned in the document. These and other uncertainties with which the skilled person was confronted were outlined in decision T 903/05 of 30 August 2007 (see paragraphs 24.1 to 24.3), in which the disclosure content of the present patent was considered as the starting point for the assessment of inventive step in respect of the use of specific telomerase peptides for the treatment or prophylaxis of cancer.

38. As concerns the further evidence on which appellants I relied, the board observes that the authors of the three declarations (Prof Wraith, Dr Dahm and Dr Grey, respectively) stressed how important the cloning of the gene encoding the human telomerase was for the development of new therapeutic strategies because it opened up **the possibility** of providing immunotherapies against human disease conditions in which the telomerase is involved, in particular cancer. This the board has no reason to doubt. However, providing the

telomerase sequence information, which is, possibly, a first step for developing cancer immunotherapies, cannot be equated to disclosing how to carry out the invention claimed in claim 44, i.e. how to develop a vaccine that elicits an immune response on the basis of an immunogenic peptide of human telomerase.

39. After careful consideration of the disclosure content of the application as filed and the evidence put forward by the parties, the board shares the view of the opposition division that the invention as claimed in claim 44 has not been disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In view of the fact that the application as filed does not disclose any telomerase peptide which may - plausibly - be regarded as a suitable candidate for a vaccine, and in view of the complete absence in the application as filed of both technical information as to how to identify possible candidate peptides, and instructions on how to proceed in case of failure, the board considers that, in the present case, identifying immunogenic fragments of the telomerase protein suitable for the manufacture of a vaccine by a trial and error procedure constitutes an undue burden to a person skilled in the art.
40. Consequently, the requirement of Article 83 EPC is considered not to be fulfilled.

Auxiliary requests 3 and 4 - Article 83 EPC

41. The adverse findings on Article 83 EPC in respect of the invention claimed in claim 44 of auxiliary request 2 (see paragraphs 34 to 40 above) apply equally

to the identical claim 44 of each of the auxiliary requests 3 and 4. Thus, neither of these requests can serve as a basis for the maintenance of the patent in amended form.

Auxiliary request 5

42. The set of claims according to auxiliary request 5 differs from the claims as granted in that claims 44, 46 and 47 have been deleted and claim 45 renumbered as claim 44. The claims are identical to those of auxiliary request 3 in opposition proceedings, which in the view of the opposition division, fulfilled the requirements of the EPC.
43. At the oral proceedings before the board, appellant II declared that the objections to claims other than claims 1, 44, 46 and 47, which had been raised for the first time in appeal proceedings, were not pursued further. Except for the objections to claim 1 under Article 83 EPC (see paragraphs 30 to 33 above), no other objections were raised in respect of this request. Since for the reasons given in connection with claim 1 of auxiliary request 2, the requirement of Article 83 EPC is considered to be fulfilled, the findings of the opposition division that the amended claims and the invention to which they relate meet the requirements of the EPC, and that the patent can be maintained in amended form, are considered to be correct. Consequently, the appeals of the patent proprietors and the opponent must be dismissed.

Order

For these reasons it is decided that:

1. Appellants I's request to correct the notice of appeal and the statement of grounds of appeal in that the name of the co-proprietor - The Regents of the University of Colorado - is indicated as co-appellant is allowed.
2. Both appeals are admissible.
3. Both appeals are dismissed.

The Registrar:

The Chairman:

A. Wolinski

R. Moufang