Case Number: T 0903/05 - 3.3.04
Application Number: 99928238.7
Publication Number: 1093381
IPC: A61K 38/45
Language of the proceedings: EN
Title of invention: Antigenic peptides derived from telomerase
Patentee: GemVax AS
Opponent: Geron Corporation
Headword: Telomerase peptides/GEMVAX
Relevant legal provisions: EPC Art. 123(2)(3), 84, 83, 87 to 89, 54, 56
EPC R. 57a
Keyword: "Right to priority (yes)"
"Inventive step (yes)"
Decisions cited: G 0002/98, T 1329/04
Catchword: -
Case Number: T 0903/05 - 3.3.04

DECISION
of the Technical Board of Appeal 3.3.04
of 30 August 2007

Appellant I: 
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(Patent Proprietor)

Representative: 
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Appellant II: 
Geron Corporation
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(Opponent)

Representative: 
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Decision under appeal: 
Interlocutory decision of the Opposition
Division of the European Patent Office posted
13 May 2005 concerning maintenance of the

Composition of the Board:
Chairman: M. Wieser
Members: R. Gramaglia
R. Moufang
Summary of Facts and Submissions

I. Appeals were lodged by the Proprietor (Appellant I) and the Opponent (Appellant II) against the interlocutory decision of the Opposition Division dated 13 May 2005 according to which European patent No. 1 093 381 claiming priority from NO 983141 filed on 8 July 1998 could be maintained in amended form on the basis of claims 1 to 15 of the third auxiliary request before it (Articles 102(3) and 106(3) EPC).

II. The Board expressed its preliminary opinion in a communication dated 8 February 2007.


IV. On 30 August 2007, oral proceeding took place, during which Appellant I requested to consider the former seventeenth auxiliary request as new main request and withdrew all other claim requests on file.

V. This request consists of 13 claims. Claims 1, 2 and 5 to 7 read as follows:

"1. The use of a peptide for the manufacture of a medicament for the treatment or prophylaxis of cancer, the peptide consisting of the sequence EARPALTSRLRFIPK (SEQ ID NO:2), DGLRPIVNMĐYVVGR (SEQ ID NO:3), GVPYEYGCVVNLKTVVNF (SEQ ID NO:4), ILAKFLHWL (SEQ ID NO:9) or ELLRSFFYYV (SEQ ID NO:10), the treatment or prophylaxis comprising generating a T cell response, the response being against the peptide EARPALTSRLRFIPK (SEQ ID NO:2), DGLRPIVNMĐYVVGR (SEQ ID NO:3),
GVPEYGCVNLRTVVF (SEQ ID NO:4), ILAKFLHWL (SEQ ID NO:9) or ELLRSFFYV (SEQ ID NO:10) or a fragment thereof, at least 8 amino acids long, producible after processing by an antigen presenting cell."

"2. The use of a nucleic acid for the manufacture of a medicament for the treatment or prophylaxis of cancer, in which the nucleic acid is capable of encoding a peptide consisting of the sequence EARPALLTSRLRFIPK (SEQ ID NO:2), DGLRPVPNMDYVVGAR (SEQ ID NO:3), GVPEYGCVNLRTVVF (SEQ ID NO:4), ILAKFLHWL (SEQ ID NO:9) or ELLRSFFYV (SEQ ID NO:10), the treatment or prophylaxis comprising generating a T cell response, the response being against the peptide EARPALLTSRLRFIPK (SEQ ID NO:2), DGLRPVPNMDYVVGAR (SEQ ID NO:3), GVPEYGCVNLRTVVF (SEQ ID NO:4), ILAKFLHWL (SEQ ID NO:9) or ELLRSFFYV (SEQ ID NO:10) or a fragment thereof, at least 8 amino acids long, producible after processing by an antigen presenting cell."

"5. Use according to any one of Claims 1 to 4 wherein the medicament is a pharmaceutical composition comprising the peptide or nucleic acid, together with a pharmaceutically acceptable carrier or diluent."

"6. Use according to any one of Claims 1 or 3 to 5 wherein the medicament comprises at least one peptide consisting of the sequence EARPALLTSRLRFIPK (SEQ ID NO:2), DGLRPVPNMDYVVGAR (SEQ ID NO:3), GVPEYGCVNLRTVVF (SEQ ID NO:4), ILAKFLHWL (SEQ ID NO:9) or ELLRSFFYV (SEQ ID NO:10) and a pharmaceutically acceptable carrier or diluent."
"7. Use according to any of claims 2 to 5 wherein the medicament comprises at least one nucleic acid that is capable of encoding a peptide consisting of the sequence EARPALLTSRLRFIPK (SEQ ID NO:2), DGLRPIVNMMDYVVGAR (SEQ ID NO:3), GVPEYGCVVNLRTVVVF (SEQ ID NO:4), ILAKFLHWL (SEQ ID NO:9) or ELLRSFFYV (SEQ ID NO:10) and a pharmaceutically acceptable carrier or diluent."

Claims 3, 4 and 8 to 10 refer to preferred embodiments of the uses according to the independent claims 1 or 2.

Claim 11 refers to a method of generating T lymphocytes capable of recognizing and destroying tumour cells in a mammal, whereby a peptide of SEQ ID NO: 2, 3, 4, 9 or 10 is used.

Claim 12 refers to a telomerase specific T lymphocyte generated by a method according to claim 11.

Claim 13 refers to a use of a combination of a telomerase peptide of SEQ ID NO: 2, 3, 4, 9 or 10 and a peptide capable of inducing a T cell response against an oncogene or mutant tumour suppressor protein or peptide for the manufacture of a medicament for the treatment or prophylaxis of cancer.

Claims 1 and 2 are essentially identical to claims 1 and 2 as considered to comply with the requirements of the EPC by the Opposition Division.
VI. The following documents are mentioned in the present decision:

D1: Vonderheide et al., Immunity (1999) 10: 673-679

D2: WO 98/14593


D29: Results of searches of HLA-A1, A2, A3, B7, B8, B27, B35 and B40 peptide motifs using Parker's algorithm on the BIMAS website


D31: Appella et al., Biomedical Peptides, Proteins and Nucleic acids (1995) 1: 177-184


D34: Ruppert et al., Cell (1993) 74: 929-937

D35: Identification of peptides having HLA-A2.1 binding motif in telomerase protein

D40: Minev et al., P.N.A.S. USA (2000) 97: 4796-4801

D41: Cibotti et al., P.N.A.S. USA (1992) 89: 416-420

D45: WO 00/25813 (with priority document D45A)


VII. The submissions by Appellant II, insofar as they are relevant to the present decision, can be summarized as follows:

Amendments (Article 84 and Rule 57a EPC)

- Amended claims 6 and 7 did not comply with Article 84 EPC. They had exactly the same scope as claim 5 and were thus redundant, and consequently unclear. Furthermore, the amended claims did not fulfil the requirements of Rule 57a EPC.

Right to priority (Articles 87 to 89 EPC)

- The priority was not validly claimed since the priority document did not relate to the same invention as the patent in suit. The priority document did not contain any experimental results which made plausible that the invention now claimed worked. Instead, it merely disclosed a list of 242 peptides, which list resulted from running the telomerase amino acid sequence through the Parker algorithm. In the priority document, there was no ranking of the peptides according to usefulness or preference. In order to arrive at
the invention now claimed, a selection had been made, which had changed the invention.

- Opinion G 2/98 of the Enlarged Board of Appeal (OJ EPO 2001, 413) concerned the question of extra features in the claims; it did not address the question at issue in the present case.

- It would be unfair to maintain the claims to the five specific peptides on the basis of a technical effect and to allow Appellant I to claim priority from a document in which no such technical effect was demonstrated.

**Inventive step (Article 56 EPC)**

- The closest prior art was document D2, which referred to telomerase peptides and proteins and suggested eliciting a Class I MHC restricted cytotoxic lymphocyte response against telomerase. This established a motivation for the skilled person to identify T cell epitopes of telomerase and to try them as vaccines. The technical problem was to identify telomerase proteins or peptides suitable for use as a vaccine.

- Concerning the peptides of SEQ ID NOs: 2, 3 and 4, there was no evidence on file that they actually solved the problem of treating cancer. It had not been shown that these peptides could be administered to a patient without being degraded by the proteases present in vivo.
In view of document D2, it would have been obvious for the skilled person to turn to either document D9 or D16, or any of documents D30 to D34, to analyse the amino acid sequence of telomerase, to identify candidate peptides, and to try whether they solved the problem posed. By applying the Parker algorithm of document D9, the skilled person would have arrived at the peptides of SEQ ID NOs: 9 and 10, as evidenced by documents D29 and D35.

A skilled person would not have been deterred by the fact that the telomerase was a self antigen. Appellant I had not established that a technical prejudice against using high affinity epitopes of self antigens existed in the prior art.

VIII. The submissions by Appellant I, insofar as they are relevant to the present decision, can be summarized as follows:

**Amendments (Article 84 and Rule 57a EPC)**

- Claims 6 and 7 were not redundant since they referred to a medicament, not necessarily a pharmaceutical composition as claim 5. There was furthermore no redundancy as claim 6 related only to peptides whereas claim 7 related only to nucleic acids.

**Right to priority (Articles 87 to 89 EPC)**

- The wording used in the claims was disclosed in the priority document. The peptides themselves
were the core of the invention, and also the link between the peptides and the disease, i.e. cancer. As these were disclosed in the priority document, the priority was validly claimed. The invention had not changed by the data present in the application.

**Inventive step (Article 56 EPC)**

- Document D2 was the closest prior art. The technical problem was the production of specific telomerase peptides suitable for use in the treatment of cancer.

- The problem was solved by the peptides of SEQ ID NOs: 2, 3 and 4, as there were strong indications that they were useful in treating cancer.

- Arriving at the claimed invention was not obvious. Starting from document D2, it was uncertain for a skilled person whether it would be possible to generate a T cell response against the self protein telomerase. In view of the disclosure in documents D46 and D41, the skilled person would have been drawn to look for low affinity peptides. There existed some confusion in the art concerning this issue as could be seen from documents D30 to D33. Although no technical prejudice existed in the art, it would nevertheless not have been obvious to use high affinity peptides. Further, document D2 did not mention the use of any algorithm and did not suggest eliciting a Class II MHC response.
IX. Appellant I (Patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of claims 1 to 13 of the new main request (filed as seventeenth auxiliary request with the letter dated 29 June 2007).

Appellant II (Opponent) requested that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

Amendments - Articles 123(2)(3) and 84 EPC and Rule 57a EPC

1. No objections were raised by Appellant II under Article 123(2) and (3) EPC with respect to the subject-matter of the claims of the new main request. The Board is satisfied that the amendments fulfil the requirements of Article 123(2) and (3) EPC.

2. The Board furthermore considers that the amendments comply with Rule 57a EPC since they are occasioned by the ground of opposition specified in Article 100(c) EPC.

3. Moreover, the amendments to the claims are accepted by the Board to be clear under Article 84 EPC. Although there is some redundancy in the wording of claims 6 and 7 when compared to the preceding claims, the Board considers that, in the present case, this does not give rise to a lack of clarity. It is furthermore common practice to allow dependent claims relating to only part of the subject-matter of preceding claims.
Sufficiency of disclosure (Article 83 EPC)

4. During the oral proceedings, Appellant II declared that the argument concerning Article 83 EPC was not pursued. The Board thus has no reason to doubt that the claimed invention is sufficiently disclosed.

Right to priority (Articles 87 to 89 EPC)

5. In view of document D45, which would be relevant prior art under Article 54(3) and (4) EPC only if the priority date of the patent in suit was not validly claimed, it needs to be established whether the patent, with respect to the claimed subject-matter, is entitled to its priority date.

6. The claims relate to the use of a telomerase peptide consisting of the sequence of SEQ ID NOs: 2, 3, 4, 9 or 10 for the manufacture of a medicament for the treatment or prophylaxis of cancer, the treatment or prophylaxis comprising generating a T cell response.

The priority document discloses the use of telomerase peptides for use in a method of treatment or prophylaxis of cancer, in which a T cell response is generated (see for instance page 10, lines 17 to 20 or claims 1 and 2 of the priority document). Among the preferred peptides are those of SEQ ID NOs: 2 to 4 (see claim 11 of the priority document), 9 (see claim 12) and 10 (see claim 10). These peptides are also part of the list of peptides disclosed in Tables 1 and 2 referred to on page 12, lines 27 to 33 of the priority document.
7. The content of the priority document mainly differs from that of the patent in suit in that it lacks the experimental results contained in paragraphs [0073] to [0077] on pages 9 and 10 and the corresponding Figures of the patent in suit, which relate to the peptides of SEQ ID NOs: 2, 3, 4, 9 and 10.

8. Appellant II has not disputed that the wording of the claims could be derived from the priority document, but argued that the claims did not relate to the same invention since the priority document lacked any experimental data which made plausible that the invention now claimed worked.

9. In accordance with Article 87 EPC, a European patent application is only entitled to priority in respect of "the same invention" as was disclosed in the previous application. The requirement of claiming priority of the same invention has been treated by the Enlarged Board of Appeal in its opinion G 2/98 (supra). It was stated therein that priority was to be acknowledged only if the skilled person could derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole. In point 8.4 of the reasons, it was furthermore stated that "[i]f the invention claimed in a later European patent application constitutes a so-called selection invention - i.e. typically, the choice of individual entities from larger groups or of sub-ranges from broader ranges of numerical values - in respect of the subject-matter disclosed in a first application whose priority is claimed, the criteria applied by the EPO with a view to assessing novelty of
selection inventions over the prior art must also be considered carefully when assessing whether the claim in the European patent application is in respect of the same invention as the priority application within the meaning of Article 87(1) EPC. Otherwise, patent protection for selection inventions, in particular in the field of chemistry, could be seriously prejudiced if these criteria were not thoroughly complied with when assessing priority claims in respect of selection inventions. Hence, such priority claims should not be acknowledged if the selection inventions in question are considered "novel" according to these criteria."

10. The Board considers it of utmost importance to strictly apply the criteria set out by the Enlarged Board of Appeal when assessing entitlement to priority. In the present case, the selection of the specific peptides of SEQ ID NOs: 2, 3, 4, 9 and 10 from the disclosure of the priority document is not considered to result in novel subject-matter since the selection is made from only one list of entities, i.e. the preferred peptides specified in the claims and in Tables 1 and 2 of the priority document. The Board is therefore convinced that the claimed subject-matter is directly and unambiguously derivable from the priority document in the sense of opinion G 2/98.

11. Since the enablement of the disclosure of the priority document has explicitly not been challenged by Appellant II, the Board does not consider it appropriate to doubt that the priority document discloses the claimed invention in an enabling way. Beyond the issue of enablement, the Board sees no legal basis for imposing additional criteria such as the
presence of experimental data in the priority document which make plausible that the invention would work. The Board is furthermore convinced that the experimental data which are present in the patent and not in the priority document do not change the nature of the invention disclosed.

12. Appellant II submitted that in view of decision T 1329/04 of 28 June 2005, it would be necessary that the priority document contained experimental data which made plausible that the invention now claimed worked. However, said decision is concerned with the question of inventive step and is therefore not relevant for the present issue of entitlement to priority.

13. Therefore, the Board concludes that the priority date of the patent in suit is validly claimed.

14. Consequently, document D45 does not constitute prior art under Article 54(3) and (4) EPC.

**Novelty (Article 54 EPC)**

15. Appellant II has not disputed the novelty of the subject-matter now claimed over the relevant prior art. The Board has no reason to doubt that the claimed invention complies with Article 54 EPC.

**Inventive step (Article 56 EPC)**

16. Both parties submitted that document D2 represents the closest prior art document, and the Board agrees that this document is the most appropriate starting point for the assessment of inventive step.
17. Document D2 relates to the catalytic subunit of human telomerase (hTRT) and to DNA encoding it. On page 100, lines 19 to 29, it is stated under the heading "Vaccines and Antibodies": "Immunogenic peptides or polypeptides having an hTRT sequence can be used to elicit an anti-hTRT immune response in a patient (i.e., act as a vaccine). Exemplary immunogenic hTRT peptides and polypeptides are described infra in Examples 6 and 8. An immune response can also be raised by delivery of plasmid vectors encoding the polypeptide of interest (i.e., administration of "naked DNA"). The nucleic acids of interest can be delivered by injection, liposomes, or other means of administration. In one embodiment, immunization modes that elicit in the subject a Class I MHC restricted cytotoxic lymphocyte response against telomerase expressing cells are chosen. Once immunized, the individual or animal will elicit a heightened immune response against cells expressing high levels of telomerase (e.g., malignant cells)."

18. In view of this prior art, the technical problem to be solved by the invention of claim 1 was the provision of telomerase peptides suitable for use as a vaccine against cancer.

Inventive step with respect to the claimed subject-matter relating to the peptides of SEQ ID NOs: 2, 3 and 4

19. Appellant II contested that the peptides of SEQ ID NOs: 2, 3, and 4 solved the problem posed, since there were no data in the patent showing that the peptides would be suitable to treat cancer in vivo.
Figures 2 to 4 and the corresponding explanations in paragraphs [0076] and [0077] of the patent in suit show that the proliferation of peripheral blood T cells from a colon cancer patient was successfully stimulated with the peptide of SEQ ID NO: 4, and that tumour infiltrating lymphocytes obtained from a patient with pancreatic cancer proliferated specifically in response to the peptides of SEQ ID NOs: 2 and 3.

Thus, contrary to the opinion of Appellant II, the Board is convinced that the data presented in the patent indicate that the peptides are useful candidates as vaccines for the treatment of cancer. In the absence of any evidence to the contrary, the Board therefore decides that the technical problem has been solved by the subject-matter of claim 1 when relating to the peptides of SEQ ID NOs: 2, 3 and 4.

20. Document D2, being the closest prior art, explicitly suggests eliciting a Class I MHC restricted cytotoxic lymphocyte response against telomerase expressing cells, but does not mention the possibility of eliciting a Class II MHC restricted T cell response against telomerase. However, the peptides of SEQ ID NOs: 2, 3 and 4, which are either 16 or 18 amino acids long, bind Class II MHC molecules, and would not be suitable to elicit a Class I MHC restricted T cell response as suggested in document D2. Since there is furthermore no other prior art document on file which mentions the possibility of eliciting a Class II MHC restricted T cell response against telomerase, the Board decides that it was not obvious for a skilled person to arrive at the subject-matter of claim 1 relating to the peptides of SEQ ID NOs: 2, 3 and 4.
Inventive step with respect to the claimed subject-matter relating to the peptides of SEQ ID NOs: 9 and 10

21. Figure 1 and the corresponding explanations in paragraphs [0073] to [0075] demonstrate the induction of telomerase reactive cytotoxic T lymphocytes in HLA-A2(A2/Kb) transgenic mice immunized with the peptides of SEQ ID NOs: 9 and 10. This indicates that these peptides may be used as a cancer vaccine in humans carrying HLA-A2 and other HLA class I molecules capable of binding these peptides. Therefore, the Board is satisfied that the technical problem has been solved by the subject-matter of claim 1 when relating to the peptides of SEQ ID NOs: 9 and 10. This has in fact not been contested by Appellant II.

22. It remains to be established whether this subject-matter was rendered obvious to the skilled person by the state of the art at the priority date.

23. The Board considers that starting from the above cited passage on page 100 of document D2 (see point 16), a skilled person would turn to Examples 6 and 8 of the same document when seeking to provide suitable peptides. Example 6 concerns the "design and construction of vectors for expression of hTRT proteins and polynucleotides", but neither discloses telomerase peptides which elicit a T cell response against telomerase, nor does it provide a teaching how such peptides could be obtained. Example 8 concerns the "production of anti-hTRT antibodies", and likewise provides the skilled person with no assistance as to
how to identify telomerase peptides which elicit a T cell response against telomerase.

24. Document D2 makes no mention of the Parker algorithm (as disclosed in document D9), or any other algorithm useful for identifying peptides that bind MHC molecules. Although the skilled person could have turned to document D9 in order to apply the Parker algorithm to the telomerase protein and subsequently test whether any of the resultant peptides solved the technical problem, the Board takes the position that he or she would not actually have done so in view of the following considerations.

24.1 First of all, the skilled person could not know from document D2 or any other prior art document whether it would really be possible to elicit a T cell response against the self protein telomerase in a patient, since it was known that T cells which bind self proteins are eliminated during T cell development from the T cell repertoire (see for instance document D37, page 1247). Furthermore, a skilled person would have been aware that even if a peptide capable of eliciting a T cell response against telomerase could be found, there would still be some uncertainty whether it would also be effective against cancer.

24.2 When attempting to identify candidate peptides, the skilled person would furthermore have been confronted with uncertainty as to whether dominant or subdominant epitopes would be more likely to be suitable to elicit a T cell response against a self antigen such as telomerase. The prior art contained contradictory remarks in this respect. This is particularly apparent
from document D30, a review article concerned with approaches to develop peptide based vaccines to treat cancer. The document reports in the paragraph bridging columns 1 and 2 of page 332 that experiments with transgenic mice "demonstrated that only those peptides that bind to HLA-A2.1 with a high or intermediate affinity (IC_{50} < 500 nM) are capable of eliciting a CTL response following immunization", whereas page 334, column 1, paragraph 1, states under the heading "Overcoming immune tolerance" that "it was found that the immunodominant peptides (...) were the peptides to which tolerance had been induced, but that sub-dominant and 'cryptic' epitopes (...) have not induced a state of tolerance and were therefore immunogenic when used as peptide antigens". The next paragraph further states that "[s]ince most immunodominant epitopes are high affinity binders, one strategy to help identify sub-dominant epitopes is to concentrate on 'intermediate to low' binding peptides as potential immunogens". The Board considers that from this disclosure, a skilled person would have assumed that in order to elicit a T cell response against the self protein telomerase, peptides with dominant epitopes should be avoided.

24.3 This view is also supported by document D46 which states that "[i]mmunization to self proteins usually fails to elicit immunity" and that "[i]t has been proposed that the autologous T cells recognize and become tolerant to the dominant epitopes of self proteins, but "ignore" the subdominant epitopes. (...) Immunity to subdominant epitopes can be elicited by immunization to proteins truncated to not contain the dominant epitopes or to peptides representing the
The Board thus takes the position that from the prior art, a skilled person either would have expected telomerase peptides which strongly bind Class I MHC molecules to be less promising when aiming at eliciting a T cell response against telomerase, or would at least have evaluated it to be highly uncertain whether this kind of peptides would lead to success. Since the Parker algorithm as disclosed in document D9 aims at identifying peptides with strong binding affinities for Class I MHC molecules, the Board concludes that the skilled person would not have applied this algorithm to the telomerase protein disclosed in document D2.

Appellant II has submitted that the inventors did not face any problems with self tolerance, that the patent in suit did also not refer to this problem, and that no technical prejudice against using peptides which strongly bind Class I MHC molecules had been established.

With respect to this argumentation, the Board observes that what needs to be considered when evaluating inventive step is the situation that a person of ordinary skill in the art would have been confronted with in view of the prior art at the priority date. If, when developing the invention, the inventors took a certain path and succeeded without facing certain problems, this does not mean that the path chosen was straightforward or obvious having regard to the state of the art. As pointed out in numerous decisions by the Boards of Appeal, any ex post facto analysis has to be
strictly avoided in the assessment of inventive step
(see Case Law of the Boards of Appeal of the European

26. It has further been pointed out by Appellant II that
the authors of documents D1 and D40, which documents
were published after the priority date, applied the
Parker algorithm to the amino acid sequence of
telomerase when aiming at generating a T cell response
against telomerase. However, this cannot convince the
Board that to proceed in this way would have been
obvious to a person of ordinary skill in the art in
view of the prior art published before the priority
date.

27. For the reasons set out above, the subject-matter of
claim 1 is considered to involve an inventive step.
Since claim 2 relates to the use of nucleic acids
encoding the peptides of SEQ ID NOS: 2, 3, 4, 9 or 10,
and since claims 3 to 13 are either dependent on
claim 1 and/or claim 2, or relate to subject-matter
making use of said peptides, the Board likewise
considers the subject-matter of claims 2 to 13 to
involve an inventive step.
Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent in amended form on the basis of claims 1 to 13 of the new main request filed as seventeenth auxiliary request with letter dated 29 June 2007 and a description to be adapted thereto.

The Registrar:  
The Chairman:

P. Cremona  
M. Wieser