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Datasheet for the decision of 21 September 2023

Case Number: T 1515/20 - 3.3.04

Application Number: 16195355.9

Publication Number: 3167888

IPC: A61K31/7105, A61K38/00, A61K39/395, A61P7/06, C07K16/18, A61K9/00

Language of the proceedings: EN

Title of invention:
Treatment of paroxysmal nocturnal hemoglobinuria patients by an inhibitor of complement

Applicant:
Alexion Pharmaceuticals, Inc.

Headword:
Inhibitor of complement / ALEXION PHARMACEUTICALS

Relevant legal provisions:
EPC Art. 54, 56, 76(1), 83, 123(2)
EPC R. 139
RPBA 2020 Art. 12(4), 12(6), 13(2)

Keyword:
Added subject-matter (yes) - main request and auxiliary request 4
Admittance (no) - auxiliary requests 1 to 3
Added subject-matter (no), sufficency, novelty inventive step (yes) - auxiliary request 5

Decisions cited:
G 0003/89, G 0011/91, G 0002/21

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Case Number: T 1515/20 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 21 September 2023

Appellant: (Applicant)	Alexion Pharmaceuticals, Inc. 100 College Street New Haven, CT 06510 (US)
Representative:	J A Kemp LLP 80 Turnmill Street London EC1M 5QU (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 11 February 2020 refusing European patent application No. 16195355.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	M. Pregetter
Members:	B. Claes
	L. Bühler
	B. Rutz
	A. Bacchin

Summary of Facts and Submissions

I. The appeal of the applicant (appellant) lies from the decision of the examining division refusing European patent application No. 16 195 355.9 entitled "*Treatment of paroxysmal nocturnal hemoglobinuria patients by an inhibitor of complement*". The application is a divisional application of European patent application No. 11 001 632.6, which itself is a divisional application of European patent application No. 07 753 249.7 filed under the PCT as an international patent application ("application as filed") published as WO 2007/106585.

II. The examining division decided that claim 1 of the main request and of auxiliary requests 1 to 3 did not meet the requirements of Articles 76(1) and 123(2) EPC.

III. With the statement of grounds of appeal the appellant submitted sets of claims of a main request and auxiliary requests 1 to 11 and four further documents. Except for the set of claims of the main request and auxiliary requests 4, 6 and 10, which were identical to the sets of claims of the main and auxiliary requests 1 to 3, respectively, dealt with by the examining division, the sets of claims of the other auxiliary requests were new to the proceedings. The appellant submitted arguments as to why the examining division's decision was wrong in respect of the requests dealt with in it, and why the new requests were allowable.

IV. The appellant was summoned to oral proceedings and subsequently the board issued a communication under Article 15(1) RPBA setting out its preliminary opinion

on matters that seemed to be of particular significance for the decision.

V. During the oral proceedings the appellant filed new sets of claims of the main request and of auxiliary request 6. At the end of the oral proceedings, the Chair announced the decision of the board.

VI. The wording of claim 1 of the requests insofar as it is relevant for the decision and ultimately dealt with by the board is reproduced at the beginning of the corresponding parts of the Reasons for the Decision below. The appellant's relevant arguments relating to these requests are also summarised in these parts.

VII. For assessing the requirements of Articles 76(1) and 123(2) EPC the board makes reference to the text of the international patent application (see section I.). The passages referred to are identical to the corresponding passages in the parent application and the application under consideration.

VIII. The following documents are referred to in this decision:

D1: US 2005/0191298

D6: CAS Database registry for Eculizumab (RN 219685-50-4, 14 February 1999)

D7: Thomas *et al.* (1996), Molecular Immunology, Vol. 33, No. 17/18, pages 1389 to 1401

D11: US 6,355,245

D12: Declaration by Dr Leonard Bell

D18: Experimental report filed on 16 January 2018

D28: Annotated version of original CAS Registry No. 219685-50-4 obtained from http://commonchemistry.org/ showing the errors in the sequence

IX. The appellant (applicant) requested that the decision under appeal be set aside and a patent be granted with the set of claims of the main request filed during the oral proceedings, or alternatively, with the set of claims of one of auxiliary requests 1 to 5, filed with the statement of grounds of appeal, auxiliary request 6, filed during the oral proceedings and auxiliary requests 7 to 11, filed with the statement of grounds of appeal.

Reasons for the Decision

Main request

Admittance

1. The request was filed during the oral proceedings and was admitted into the proceedings (Article 13(2) RPBA). However, in view of the fact that the request was held to be unallowable (see below), there is no need for the board to provide reasons for having admitted it.

Claim 1 - amendments - correction (Rule 139 EPC) and added subject-matter (Articles 76(1) and 123(2) EPC)

2. Claim 1 of the main request differs from claim 1 of the main request dealt with by the examining division

solely on account of 214 being replaced with 236 in the context of the range of residues in SEQ ID NO: 4, and reads as follows:

"*1. An antibody that binds C5 comprising a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of* ***residues 23 to 236 of SEQ ID NO: 4***." (emphasis added by the board)

3. What is claimed is an antibody that binds C5 comprising "a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of residues 23 to 236 of SEQ ID NO: 4". It is undisputed that the only references to SEQ ID NO: 4 in the disclosure of the application as filed are found on page 5, lines 30 to 33 ("*In certain embodiments, the antibody that binds C5 or an active antibody fragment thereof comprises a heavy chain and a light chain, wherein the heavy chain consists of SEQ ID NO: 2 and the light chain consists of SEQ ID NO: 4*") and on page 44, where the amino acid sequence of "SEQ ID NO: 2 — Eculizumab Heavy chain" as well as the 236 amino acid-long sequence of "SEQ ID NO: 4 - Eculizumab Light chain" are reproduced. It is equally undisputed that the application as filed does not explicitly disclose the length limitation "residues 23 to 236" for SEQ ID NO: 4.

4. The appellant submitted, however, that the length limitation "residues 23 to 236" for SEQ ID NO: 4 in the claim to define the antibody that binds C5 corrected an obvious error which met the requirements of Rule 139 EPC and Article 123(2) EPC.

5. In opinion G 3/89 (OJ EPO 1993, 117) and decision G 11/91 (OJ EPO 1993, 125), the Enlarged Board of Appeal held that corrections under Rule 88, second

sentence, EPC 1973 (now Rule 139, second sentence, EPC) were special cases of an amendment within the meaning of Article 123 EPC and fell under the prohibition of extension laid down in this rule. In accordance with the established case law of the boards of appeal, in the case of a proposed amendment under Article 123(2) EPC or a correction under Rule 139 EPC, the factual disclosure of the patent application as filed has to be established to a rigorous standard, namely the standard of certainty "beyond reasonable doubt" (see Case Law of the Boards of Appeal, 10th edition, 2020, "CLBA", II.E.5).

6. Based on the Enlarged Board's rulings in the opinion and the decision, for a correction in the description, the claims or the drawings to be allowable under Rule 139, second sentence, EPC, the boards apply a two-step approach (see also CLBA, II.E.4.2) in which both of the following must be established:

(i) it is obvious that the application as filed contains such an obvious error that a skilled person is in no doubt that this information is not correct and cannot be meant to read as such. Accordingly, it must be obvious that an error is present and has to be objectively recognisable by the skilled person using common general knowledge; and

(ii) the skilled person using common general knowledge would directly and unequivocally ascertain the precise proposed correction. The correction of the error should be obvious in the sense that it is immediately evident that nothing else would have been intended than what is offered as the correction.

7. Concerning the first aspect of the two-step approach, the appellant submitted, and the board can agree, that it was common general knowledge that antibodies are secreted proteins produced from precursor light chain and heavy chain polypeptides in cells, which precursors each comprise a signal peptide and a mature polypeptide. The signal peptides are cleaved off in the endoplasmic reticulum (ER) of the expressing cell and the mature polypeptide then folds to form the mature protein. The board also agrees that, commonly, recombinant chimeric and humanised antibodies as claimed are produced in transfected mammalian cells from DNA vectors and that monoclonal antibodies may be produced in transfected cells, such as CHO cells and NSO cells (see also explicit disclosure in the description of the application as filed on page 19, lines 6 to 7 that monoclonal antibodies may be produced in transfected cells, such as CHO cells and NSO cells).

8. The appellant concluded that the skilled person thus knew "*with certainty*" that a given engineered therapeutic antibody comprising a heavy chain and a light chain is produced in cells and therefore that a "*signal peptide was never present*" in the therapeutic antibody and continued that, based on the common general knowledge, the skilled person would immediately recognise the signal peptide in SEQ ID NO: 4 in view of the starting methionine residue followed by a stretch of 21 mainly hydrophobic amino acids and the fact that the peptide sequence of 236 residues was longer than the average light chain of a mature antibody, which ranged from 211 to 217. The skilled person would therefore have immediately recognised that defining the antibody as comprising a light chain variable region consisting of SEQ ID NO: 4 constituted an error.

9. The board is not convinced by the appellant's arguments that criterion i) of the two-step approach was met, i.e. that the statement of "a light chain variable region consisting of SEQ ID NO: 4" in the application as filed on page 5 and "SEQ ID NO: 4 - Eculizumab Light chain" page 44 (see point 3.) constituted such an obvious error that a skilled person was in no doubt that this information is not correct (see point 6.).

10. First, the board has seen no arguments as to why the skilled person, when confronted with the statement "a light chain variable region consisting of SEQ ID NO: 4" as such in the disclosure of the application, would *prima facie* be alerted and consequently prompted to consider and analyse the corresponding sequence depicted on page 44 with a view to determining the presence of particular functional parts/compounds in the unannotated amino acid sequence, in this case an ER signal sequence.

11. Second, even when inspecting the sequence of SEQ ID NO: 4 depicted on page 44 and noting a starting methionine residue followed by a stretch of mainly hydrophobic amino acids (which stretch is in fact 25 amino acids long and also includes the amino acids at positions 23, 24 and 25) and the slightly above average light chain length for a mature antibody, the skilled person would not, as the appellant has alleged, immediately recognise that the depicted sequence of SEQ ID NO: 4 constituted an error because it included a signal peptide, but instead could, at best, be caused to doubt that the depicted sequence was the sequence it purported to represent. This state of doubt however, does not equate with the requirement, in the case at hand, that the skilled person has *no* doubt that the

depicted sequence is an error and cannot be intended to read as such.

12. In view of the above considerations, the board concludes that the appellant's case on criterion i) of the two-step approach in point 6. above must fail. Accordingly, for this reason alone, the two-step approach cannot lead to the conclusion that the amendment of the feature "a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4" to "a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of residues 23 to 236 of SEQ ID NO: 4" constitutes an allowable correction under Rule 139 EPC.

13. In view of the above negative conclusion on step i), the board does not deem it necessary to deal with the appellant's further arguments relating to criterion ii) of the two-step approach which, without exception, emphasise in more technical detail that the skilled person would investigate and consequently identify the exact length of a leader peptide in the depicted amino acid sequence for SEQ ID NO: 4 on page 44 of the application as filed.

14. The request for correction is thus rejected and the claim fails to meet the requirements of Articles 76(1) and 123(2) EPC.

Auxiliary request 1 - admittance

15. Claim 1 of auxiliary request 1 reads:

"*1. An antibody that binds C5, wherein the* ***antibody is eculizumab and comprises a heavy chain consisting of SEQ ID NO: 2.***" (emphasis added by the board)

16. This request was first filed in the appeal proceedings with the statement of grounds of appeal and its admittance is governed by Article 12(4) RPBA, which provides the board with the discretion to admit such requests in view of, *inter alia*, the suitability of the amendment for overcoming issues which led to the decision under appeal.

17. As compared with claim 1 of the main request (see point 2.), the claim now specifies that the C5-binding antibody is "eculizumab and comprises a heavy chain consisting of SEQ ID NO: 2", but lacks a reference to SEQ ID NO: 4. The appellant referred to the disclosure on page 5, lines 28 to 29 ("*In certain embodiments, the pharmaceutical composition comprises eculizumab*.") and on page 44 (see point 3. above) as the basis for the amendments. The board is not persuaded however that these passages provide an adequate basis for defining the C5-binding antibody by reference to "eculizumab" and SEQ ID NO: 2 without an explicit reference to SEQ ID NO: 4. Indeed, the skilled person would not directly and unambiguously derive from the disclosure on page 5, lines 31 to 33 and on page 44 (see point 3. above), using common general knowledge, a generalised "eculizumab" antibody defined solely by having a heavy chain consisting of SEQ ID NO: 2 without at the same time comprising a light chain consisting of SEQ ID NO: 4.

18. Therefore, in view of the above considerations, the amendment amounts to an undisclosed intermediate generalisation of the disclosure of the application as filed, contrary to the requirements of Articles 76(1) and 123(2) EPC. Accordingly, the amendment is not suitable for overcoming the added subject-matter issues

which the examining division raised with regard to claim 1 of the main request. The board therefore did not admit the request into the proceedings (Article 12(4) RPBA).

Auxiliary requests 2 and 3 - admittance

19. Claim 1 of auxiliary request 2 reads:

"*1. An antibody that binds C5, wherein the antibody is* ***obtainable by producing in transfected cells*** *a heavy chain consisting of SEQ ID NO: 2 and* ***a light chain consisting of SEQ ID NO: 4.***" (emphasis added by the board)

Claim 1 of auxiliary request 3 reads:

"*1. An antibody that binds C5, wherein the antibody is* ***obtainable by producing in transfected CHO or NSO cells*** *a heavy chain consisting of SEQ ID NO: 2 and* ***a light chain consisting of SEQ ID NO: 4.***"

20. As compared with claim 1 of the main request (see point 2.), claim 1 of both requests now specifies that the C5-binding antibody is obtainable by producing in transfected cells a light chain consisting of SEQ ID NO: 4, *inter alia*.

21. These requests were also first filed in the appeal proceedings and their admittance is governed by Article 12(4) RPBA (see point 16.).

22. Although the appellant in the statement of grounds of appeal explained the amendment to claim 1 and indicated a basis in the application as filed for the amendment, they did not provide reasons for only submitting them

in the appeal proceedings, and not at an earlier stage, in the examination proceedings. None of such reasons were submitted at the oral proceedings, either.

23. Furthermore, although the board had expressed in its communication that *prima facie* it was not persuaded that the amendments overcame its added subject-matter concerns in relation to claim 1 of the main request, the appellant nevertheless also refrained from providing dedicated reasons during the oral proceedings for why the amendment would overcome the added subject-matter issues of claim 1 of the main request.

24. Accordingly, the board decided not to admit and consider these requests in the appeal proceedings (Article 12(4) and (6) RPBA).

Auxiliary request 4 - added subject-matter (Articles 76(1) and 123(2) EPC)

25. Claim 1 of auxiliary request 4 reads:

"*An antibody that binds C5 comprising the heavy chain amino acid sequence shown in SEQ ID NO: 2 and* ***the light chain amino acid sequence shown in SEQ ID NO: 4.***"
(emphasis added by the board)

26. The examining division decided that, for the same reasons as for claim 1 of the main request, claim 1 of this request related to added subject-matter and did not comply with the requirements of Articles 76(1) and 123(2) EPC, *inter alia*.

27. This claim now defines the antibody as comprising "the heavy chain amino acid sequence shown in SEQ ID NO: 2 and the light chain amino acid sequence shown in

SEQ ID NO: 4". The appellant did not contest that the words "shown in" are not used in the application as filed. Nevertheless, as was submitted by the appellant, because the application as filed on page 5, lines 28 to 29 disclosed that "*In certain embodiments, the pharmaceutical composition comprises eculizumab*." and the heavy and light chain amino acid sequences of eculizumab were shown in SEQ ID NO: 2 and SEQ ID NO: 4 on page 44, respectively, and the skilled person knew that SEQ ID NO: 4 was not the mature sequence, but contained a signal peptide, the application was a direct and unambiguous basis for an antibody that comprises the heavy chain amino acid sequence shown in SEQ ID NO: 2 and the light chain amino acid sequence shown in SEQ ID NO: 4.

28. In the section on the main request (see points 2. to 14.), the board decided that the amendment of the feature "a light chain consisting of SEQ ID NO: 4" to read "a light chain consisting of residues 23 to 236 of SEQ ID NO: 4", i.e. excluding a precise 22 amino acid-long signal peptide from the N-terminus of the amino acid sequence depicted in SEQ ID NO: 4 on page 44, did not comply with the requirements of Articles 76(1) and 123(2) EPC and introduced added subject-matter. This conclusion also applies to claim 1 of this auxiliary request, as the skilled person is not considered to immediately recognise that the amino acid sequence depicted in SEQ ID NO: 4 includes both a particular signal peptide sequence and the mature light chain sequence, and thus to directly and unambiguously derive a (mature) light chain sequence shown in SEQ ID NO: 4 from the application as filed.

29. Accordingly, claim 1 of this auxiliary request does not comply with the requirements of Articles 76(1) and 123(2) EPC.

Auxiliary request 5

30. The two claims of auxiliary request 5 read:

"*1. An antibody that binds C5 comprising a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4.*

2. A pharmaceutical composition comprising the antibody of claim 1."

Admittance (Article 12(4) RPBA)

31. This request was also filed with the statement of grounds of appeal. The board admitted and considered this request in the appeal proceedings as it would *prima facie* overcome the added subject-matter issue of claim 1 of the main request (see point 14.).

Added subject-matter (Articles 76(1) and 123(2) EPC)

32. The board acknowledges that page 5, lines 30 to 33, of the application as filed provides a basis for the amendment, and the claims of the request thus accordingly comply with the requirements of Articles 76(1) and 123(2) EPC.

Sufficiency of disclosure (Article 83 EPC)

33. It is common ground that SEQ ID NO: 4 comprises an N-terminal 22 amino acid-long signal peptide sequence which is followed by the amino acid sequence for a

mature light chain starting at position 23 of the sequence.

34. Although it may be accepted that the antibody comprising the heavy chain consisting of SEQ ID NO: 2 and the mature light chain contained in SEQ ID NO: 4 binds C5 as required by the claim, *prima facie*, it can equally be accepted, however, that the skilled person may have concerns that the presence of the N-terminal 22 amino acid-long signal sequence could impair this binding property.

35. In this respect, the appellant submitted that the position of the three respective CDR sequences in SEQ ID NO: 4, which are instrumental for the specific binding properties required by the claim, is sufficiently distanced from the N-terminal signal peptide to dissuade the skilled person from having doubts that this longer light chain would also bind to C5 as required by claim 1.

36. The board accordingly concluded that the claimed antibody is sufficiently disclosed in the patent.

Novelty (Article 54 EPC)

37. None of the documentary evidence available to the board discloses an antibody as claimed. Accordingly, the claimed subject-matter is novel.

Inventive step (Article 56 EPC)

38. The application aims to provide treatments for paroxysmal nocturnal hemoglobinuria (PNH) and, in this context, provides an antibody comprising a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting

of SEQ ID NO: 4 that binds to the terminal complement protein C5 as now claimed. It is of note, however, that claim 1 does not concern the treatment of PNH, but merely the binding of the claimed antibody comprising a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4 to the terminal complement protein C5.

39. Document D1 discloses a clinical trial using a monoclonal anti-C5 antibody referred to under the trade name "eculizumab" in the context of the treatment of PNH. Eculizumab is also referred to as antibody h5G1.1-mAb (see document D1, paragraph [0052], lines 31 to 33). Document D1 does not itself disclose the sequence of "eculizumab", but refers to the disclosures in documents D7 and D11 as describing suitable anti-C5 antibodies including "eculizumab" (see document D1, paragraph [0052], lines 24 to 33). Of these, document D7 (see Figure 1) discloses amino acid sequences of VL and VH variable regions for the humanised monoclonal antibody designated "h5G1.1", which has a naturally occurring human IgG4 heavy chain constant region.

40. The board considers this humanised anti-C5 antibody disclosed in document D7 to represent the closest prior art for the purpose of assessing whether the claimed antibody which binds to the terminal complement protein C5 involves an inventive step.

41. The claimed antibody does not, however, have an IgG4 type constant region as the humanised antibody disclosed in document D7 (see page 1396, sentence bridging the columns), but instead an engineered heavy chain constant region (see page 44, SEQ ID NO: 2 and SEQ ID NO: 4) of an IgG2/4 hybrid isotype, differing in 14 amino acid positions. The differences between the

IgG4 heavy chain constant region in document D7 and the engineered heavy chain constant region of the antibody in claim 1 of the IgG2/4 hybrid isotype are shown in the alignment disclosed in paragraph 5 of document D12 (four amino acid differences in the CH1 domain, six amino acid differences in the hinge domain and four amino acid differences in the CH2 domain).

42. The appellant submitted that the technical effect of these differences was, *inter alia*, a reduced ability to stimulate undesired immune responses (reduced immunogenicity) by the claimed antibody. Indeed, as explained in document D12 (see paragraph 6 referring to document D18), the differences in the altered heavy chain constant region result in the antibody having reduced binding to Fcγ receptors such that immune responses that are undesirable for an antibody intended to shut down the terminal complement pathway are minimised, an effect which is mentioned in the application as filed (see page 5, lines 10 to 18). The board is hence satisfied that, in accordance with decision G 2/21, these post-published data from document D18 can be taken into account.

43. The board agrees with the appellant that, at least for this aspect of the technical effect of the difference, the objective technical problem solved by the claimed antibody can thus be defined as the provision of a C5-binding antibody having a reduced ability to stimulate undesired immune responses as compared with the h5G1.1 IgG4 antibody disclosed in document D7.

44. Document D7 itself does not mention anything regarding the effects of the heavy chain constant region on the properties of the antibodies. Futhermore, document D7 teaches that there was only one known allotype of IgG4

(see page 1399, right-hand column, line 28), thus in fact precluding the potential development of allo-antibodies in humans. Document D7 in fact explains why the IgG4 isotype was chosen for the full length antibody, reporting that: *"The human IgG4 isotype was chosen, as this isotype does not activate human complement (Tao et al., 1993) and there is only one known allotype of IgG4 (Ghanem et al., 1988), precluding the potential development of allo-antibodies in patients. The humanized h5G1.1 (CDR) HuG4 antibody bound to human C5 with a similar avidity as the murine antibody when assayed by ELISA (Fig. 9) and inhibited lysis of porcine aortic endothelial cells as effectively as the murine antibody, with a 1:1 molar ratio of antibody binding sites to human C5 being sufficient for inhibition (Fig. 10)."* (see page 1399, right-hand column, lines 27 to 37). This disclosure also does not motivate the skilled person to use an antibody other than the IgG4 antibody described in document D7 in view of the teaching in D7 that the human IgG4 isotype has the advantage that it does not activate human complement and has only one known allotype, precluding an immune response against the constant region of the antibody.

45. Although it teaches that constant regions may be constructed of a mixture of constant domains, document D11 equally does not suggest the specific differences between the IgG4 constant region amino acid sequence and the constant region sequence of the claimed antibody, nor does it motivate the skilled person to deviate from the unaltered, naturally occurring IgG constant regions (see column 45, lines 24 to 33).

46. The disclosure of an amino acid sequence of an antibody named "Eculizumab" and "Soliris" in the CAS Registry

public database (see document D6) before the filing date would not have provided the skilled person with the missing information, either, because, as evidenced by the appellant (see document D28), this entry contains a number of serious mistakes which would not have allowed the skilled person to combine it with the disclosure of document D7 in a meaningful way.

47. Accordingly, the solution to the problem of providing a C5-binding antibody having a reduced ability to stimulate undesirable immune responses as compared with the IgG4 antibody as disclosed in document D7 would not have been obvious to the skilled person on the filing date. Evidently, a pharmaceutical composition comprising the antibody from claim 1 would not have been obvious either.

48. In view of the above considerations, the subject-matter of both claim 1 and claim 2 involves 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 examining division with the order to grant a patent in the following form:
   - Description:
     pages 1 to 55 as filed;
   - Claims:
     No 1 and 2 of auxiliary request 5 filed with the statement of grounds of appeal;
   - Drawings:
     sheets 1/4 to 4/4 as filed;

- Sequence listings:
  SEQ ID No: 1 to 10 as filed.

The Registrar: The Chair:

I. Aperribay M. Pregetter

Decision electronically authenticated