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**Datasheet for the decision
of 1 August 2017**

Case Number: T 0231/13 - 3.2.02

Application Number: 05764574.9

Publication Number: 1874193

IPC: A61B10/00

Language of the proceedings: EN

Title of invention:

PROCESS OF STATISTIC VALIDATION OF CORNEAL ENDOTHELIUM CELLS
ANALYSED SAMPLES

Applicant:

Abib, Fernando Cesar
Godois, Ronialci
Hara, Yoshiaki

Headword:

Relevant legal provisions:

EPC Art. 52(2)(d), 56, 83, 84, 133(2)

RPBA Art. 13(1), 13(3), 15(2)

Notice of the Vice-President of DG 3 of the EPO dated
16 July 2007 concerning oral proceedings before the boards of
appeal of the EPO

Keyword:

Representation - applicant having residence outside Contracting States
Oral proceedings - postponement (no)
Late-filed main request - justification for late filing (no)
request clearly allowable (no) - adjournment of oral proceedings would have been required (yes) - admitted (no)
Claims - clarity - auxiliary request 2 (no)
Sufficiency of disclosure - auxiliary request 2 (no)
Inventive step - auxiliary request 1 (no) - mixture of technical and non-technical features - presentation of information

Decisions cited:

T 0641/00, T 1543/06

Catchword:



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Case Number: T 0231/13 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 1 August 2017

Appellant:

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Decision under appeal:

**Decision of the Examining Division of the
European Patent Office posted on 7 August 2012
refusing European patent application
No. 05764574.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
 P. L. P. Weber

Summary of Facts and Submissions

- I. The applicants have appealed the Examining Division's decision, dispatched on 7 August 2012, to refuse European patent application No. 05 764 574.9.
- II. The Examining Division held that claim 1 of the main request did not comply with Articles 84 and 83 EPC, because its subject-matter was neither clear nor sufficiently disclosed. More particularly, the defined "sample size" and its determination according to the claim were objected to. Claim 1 of the auxiliary request contained subject-matter extending beyond the content of the application as originally filed, in contravention of Article 123(2) EPC.
- III. Notice of appeal was received on 1 October 2012. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 7 December 2012.
- IV. The Board summoned the appellant to oral proceedings. In the communication accompanying the summons the Board set out its preliminary opinion. It raised objections of lack of clarity of the subject-matter of claim 1 of the main request and auxiliary request 2, in particular in relation to steps concerning the determination of a "sample size and calculated relative error", and lack of inventive step of the subject-matter of claim 1 of auxiliary request 1 as then pending.
- V. Oral proceedings took place on 1 August 2017.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request, filed during the oral proceedings

or, in the alternative, of one of auxiliary requests 2 and 1, filed with letter dated 7 December 2012, in that order.

The previous main request, consisting of the claims of the application as originally filed, was withdrawn.

At the opening of the oral proceedings the appellant requested their postponement, due to serious illness of one of the inventors who wished to attend.

VI. **Claim 1 as originally filed**, which corresponds to claim 1 of the main request on which the impugned decision is based, reads as follows:

"'PROCESS OF STATISTIC VALIDATION OF CORNEAL ENDOTHELIAL CELLS ANALYSED SAMPLES', realized by dedicated software specially developed for accomplishment of the Process from the statistical data obtained in corneal specular microscopy devices currently available in the market, characterized by, having integration among referred devices and the Process, being the software conjugated or not conjugated to the referred devices, the process taking in account patient age and accomplished from the data obtained in the referred devices, in the following sequence:

Initially, data of the clinic, examiner doctor, requesting doctor, and corneal specular microscope used in image acquisition are configured;

b. Patient data are identified: name, date of birth and age;

c. Routine to be accomplished is requested: to guide an exam being realized or to validate an already realized, past exam (needed to inform past exam date);

d. Data supplied by the specular microscopy exam are entered: endothelial density, average cellular area, number of counted cells, variation coefficient, cells with less than six, with six, and with more than six sides, and shape factor (they can be one or more than one);

e. The sampling type is selected: Standard for specular microscopes that do not calculate the variation coefficient, or Personalized in case the variation coefficient is known, when the specular microscope supplies the variation coefficient the user can choose between the Standard or Personalized sampling type;

f. Statistical power of the sample to be calculated is determined: 90% to 99% for confidence level and 10% to 1% for relative error;

g. Sample size and calculated relative error are determined;

h. Graphic and numeric demonstrations of the sample size are shown:

- Graphic and numeric demonstration of the quantity of counted cells and of the number of cells that composes the Standard Sample;

- Graphic and numeric demonstration of the quantity of counted cells and of the number of cells that composes the Personalized Sample;

- Graphic and numeric demonstration of the quantity of counted cells and, of the number of cells that composes the Standard Sample and of the number of cells that composes the Personalized Sample (simultaneously);

i. Numeric visualization of the calculated relative error determined for the number of cells that composes the chosen sample;

j. Graphic Visualization of the values found for the studied variables: endothelial density, average

cellular area, number of counted cells, variation coefficient, cells with less than six, six and more than six sides, and shape factor, presented in statistical-analytic rulers in a rectangular format with stripes (areas) positioned side by side in any direction (from **A** to **D** or from **D** to **A**), where:

A. Area indicating values above that expected for the age (located in the side opposite to dégradée color);

B. Area indicating values expected for the age;

C. Area indicating values lower than expected for the age, however within the biological reserve compatible with a normal function;

D. area indicating values considered critical for the age; the intensity of the color increases as the evaluated data becomes more critical

E. Arrow indicating the mean of the studied variable;

F. Indicates the inferior limit of the reliability interval (RI) for the studied variable;

G. Indicates the superior limit of the reliability interval (RI) for the studied variable; and

F-G segment: represents the reliability interval (RI) which is calculated as follows: $RI = \text{mean} \pm \text{relative error}$ calculated for the total sample, assuming variable length, accompanying in the used scale, the value of the calculated reliability interval, **F-G** segment and can be positioned below, within, or above the stripes that define the areas; is the

k. An area is generated for written considerations about endothelial cells morphometry, endothelial analysis and final conclusions and another clear area is created for optional description of analyzed data (endothelial density, average cellular

area, number of counted cells, variation coefficient, cells with less than six, six and more than six sides, and shape factor);

1. A clear area is generated for input of diagnosis found in the endothelial and morphometric analysis of the cornea, and another clear area is created for the optional description of the conclusion based on results evidenced by the Process, where the doctor makes considerations relative to the clinical-surgical historic; and

m. The reports are printed;

For exams accomplished under the orientation of the Process:

- Graphics: statistical-analytical rulers for each one of the studied variables (endothelial density, average cellular area, variation coefficient, percentage of cells with less than six, six and more than six sides and shape factor), individually issued for each eye;

- Sampling: Type of selected sample: standard or personalized with respective statistical power (confidence level and relative error), individually issued for each eye;

- Descriptive (mean for the studied variables and, if available, standard deviation), where the data for each eye are presented in comparative form);

- Final analysis: descriptive report at choice of the doctor responsible for the Process; or

- Complete: compounded by all four reports above described; or

To validate already accomplished exams:

- Sample analyzed with respective statistical power, individually issued for each eye; or

- Descriptive (mean of the studied variables), where data for each eye are presented in

comparative form."

Claim 1 of the present main request reads as follows:

"Corneal specular microscope configured to implement a process of statistic validation of corneal endothelial cells analysed samples, said microscope being programmed with a dedicated computer program implemented in computational means, such computer program implementing said process and having as input statistical data obtained for a single patient from a corneal specular microscope, **characterized by** said computer program being integrated in said corneal specular microscope, the process further taking in account patient age and having as input data for a single patient obtained in said corneal specular microscope,

the process comprising the following steps in the following sequence:

- a. configuring data of the clinic, examiner doctor, requesting doctor, and corneal specular microscope used in image acquisition;
- b. Identifying patient data are, such data comprising: name, date of birth and age;
- c. Requesting a routine to be accomplished, such routine comprising indication of: to guide an exam being realized or to validate an already realized, past exam (needed to inform past exam date);
- d. entering data supplied by the corneal specular microscope exam, such data comprising one or more of: endothelial density, average cellular area, number of counted cells in said sample, variation coefficient, cells with less than six, with six, and with more than six sides, and shape factor

- e. selection by a user of sampling type, such sampling type consisting of:
 - standard type, in case of said specular microscope consisting of a specular microscope that does not calculate the variation coefficient, or
 - personalized type, in case a variation coefficient is known through said specular microscope supplying the variation coefficient, wherein in such case the user can choose between the standard or personalized sampling type;
- f. determination by a user of desired statistical power of said sample to be calculated: 90% to 99% for confidence level and 10% to 1% for relative error;
- g. determination of the size of said sample, thus the sample size, obtained through:
 - taking into account patient data and epidemiologic corneal data to define a total sample, designated standard sample; or
 - taking into account the endothelial data referring to the eye of patient under analysis, defining a feedback such that, based in such values, an ideal sampling of said eye corresponding to said corneal endothelial cells analyzed samples is defined by the user, designated personalized sample;and a calculated relative error associated with said sample and obtaining a set of images of the corneal endothelium of said single patient thereby meeting said relative error;

- h. presentation of graphic and numeric demonstrations of the sample size, such demonstrations consisting of:
 - graphic and numeric demonstration of the quantity of counted cells and of the number of cells that composes said standard sample;
 - graphic and numeric demonstration of the quantity of counted cells and of the number of cells that composes said personalized sample;
 - graphic and numeric demonstration of the quantity of counted cells and, of the number of cells that composes the standard sample and of the number of cells that composes the personalized sample, simultaneously;
- i. Numeric visualization of the calculated relative error determined for the number of cells that composes the chosen sample;
- j. Graphic visualization of the values found for the studied variables: endothelial density, average cellular area, number of counted cells, variation coefficient, cells with less than six, six and more than six sides, and shape factor, presented in statistical-analytic rulers in a rectangular format with stripes (areas) positioned side by side in any direction (from A to D or from D to A), where:
 - A. Area indicating values above that expected for the age (located in the side opposite to degrade color);
 - B. Area indicating values expected for the age;
 - C. Area indicating values lower than expected for the age, however within

the biological reserve compatible with a normal function;

- D. Area indicating values considered critical for the age; the intensity of the color increases as the evaluated data becomes more critical
- E. Arrow indicating the mean of the studied variable;
- F. Indicates the inferior limit of the reliability interval (RI) for the studied variable;
- G. Indicates the superior limit of the reliability interval (Rl) for the studied variable; and
F-G segment: represents the reliability interval (Rl) which is calculated as follows: $RI = \text{mean} \pm \text{relative error}$ calculated for the total sample, assuming variable length, accompanying in the used scale, the value of the calculated reliability interval, F-G segment and can be positioned below, within, or above the stripes that define the areas; is the
- k. A area is generated for written considerations about endothelial cells morphometry, endothelial analysis and final conclusions and another clear area is created for optional description of analyzed data, such analyzed data comprising endothelial density, average cellular area, number of counted cells, variation coefficient, cells with less than six, six and more than six sides, and shape factor;
- l. A clear area is generated for input of diagnosis found in the endothelial and morphometric analysis of the cornea, and another clear area is

created for the optional description of the conclusion based on results evidenced by the process, where the doctor makes considerations relative to the clinical-surgical historic; and m. printing of a plurality of reports, such reports comprising:

- statistical-analytical rulers for each one of the studied variables (endothelial density, average cellular area, variation coefficient, percentage of cells with less than six, six and more than six sides and shape factor), individually issued for each eye;
 - type of selected sample: standard or personalized with respective statistical power (confidence level and relative error), individually issued for each eye;
 - mean for the studied variables and, if available, standard deviation, where the data for each eye are presented in comparative form;
 - descriptive report at choice of the doctor responsible for the process; or
 - compounded by all four reports above described; or
- validation of already accomplished exams:
- sample analyzed with respective statistical power, individually issued for each eye; or
 - mean of the studied variables, where data for each eye are presented in comparative form."

Apart from a few irrelevant editorial changes, **claim 1 of auxiliary request 2** corresponds to claim 1 as originally filed, except that point g of the list after the first column in the claim has been modified and

further points g.1 and g.2 have been added, now reading:

"g. Sample size and calculated relative error are determined by two ways:

g.1 - By the first way it taken in account patient data and epidemiologic corneal data to define the total sample, this method is denominated of Standard Sample;

g.2 - By the secon way, it is taken in account patient's endothelial data to make a feedback in the Process so that, based in these values, will be defined the ideal sampling for the eye in analysis, this method is denominated of Personalized Sample in order to accomplish the cornea endotelium sampling calculation;"

Claim 1 of auxiliary request 1 reads as follows:

"A process operatively coupled to a microscope device, the device configured to calculate values for variables wherein the variables comprise members selected from a group consisting of median and/or mean and standard deviation for corneal cellular density; average cellular area; variation coefficient; percentage of corneal cells with less than six sides; percentage of corneal cells with six sides; percentage of corneal cells with more than six sides; and shape factor, the process comprising: generating using the device a statistical-analytic ruler graphic for a variable wherein the ruler graphic comprises areas A, B, C and D wherein area A indicates values of the variable above that expected for age of a corneal cell sample, area B indicates values of the variable expected for age of the corneal cell sample, area C indicates values of the variable lower than expected for age of the corneal

cell sample and within a biological reserve compatible with normal corneal function, and area D indicates values of the variable considered critical for age of the corneal cell sample; generating an arrow graphic E that indicates mean of the variable for the corneal cell sample; generating a segment graphic F-G wherein an F end of the segment indicates an inferior limit of a reliability interval for the variable, wherein a G end of the segment indicates a superior limit of the reliability interval for the variable, and wherein the segment length from F to G represents a reliability interval calculated according to a mean plus and minus a relative error calculated for the corneal cell sample; and generating a report graphic that comprises at least the ruler graphic for the variable."

VII. The appellant's arguments may be summarised as follows:

Request for postponement of the oral proceedings

At the opening of the oral proceedings their postponement was requested, because one of the inventors, who wished to accompany the professional representative, could not be present due to serious illness that required medical intervention. This was proven by a medical certificate dated 28 July 2017 and filed during the oral proceedings. The request for postponement could not have been made before because the need for medical intervention had been sudden and the representative had been informed of it only the evening before the oral proceedings.

Admissibility of the main request

The main request was only filed during the oral proceedings because an important aspect of the

invention had come to light in a recent discussion with the inventor. More particularly, claim 1 of the main request had been directed to a corneal specular microscope with additional inventive features specified in steps f and g. It had been made clear that those steps were performed by the claimed microscope, which performed a process of statistic validation of analysed samples of corneal endothelial cells and provided an enhanced presentation of the results of the process.

Clarity and sufficiency of disclosure of auxiliary request 2

It was surprising that the application had been refused by the EPO, when it had not been refused in countries such as China, Japan and the United States of America.

All the terms employed in claim 1 of auxiliary request 2 were usual terms in ophthalmology or statistics. The defined sample size and relative error related to a sample of cells of the corneal endothelium. The sample size represented the number of cells contained in different images obtained by specular microscopes. Newly introduced paragraphs g.1 and g.2 specified better how sample size and relative error were determined. By performing the claimed process, an operator would set the sample size and relative error and would then obtain information indicating whether the results obtained up to a certain stage of the examination of the corneal endothelium, based on the samples analysed up to that point, could already be trusted or whether other samples were needed to reach the desired level of reliability as set by means of the sample size and relative error.

Inventive step of auxiliary request 1

Auxiliary request 1 consisted of the claims granted in the US. Claim 1 was directed to a process operatively coupled to a microscope device. The process made it possible to effectively present the variables determined by the microscope to a user. More particularly, by means of the technical features of the claimed process, graphics were produced and displayed on a single screen, which had the technical effect of enhancing the conveying of information to the user. The displaying of those graphics was therefore a technical feature to be duly considered in the assessment of inventive step.

Reasons for the Decision

1. The appeal is admissible.
2. The invention

The invention relates to corneal specular microscopy, which is used to analyse the cells in the inner tissue (endothelium) of a cornea of a patient. The quantity and morphology of these cells are responsible for maintaining the vitality of the cornea. A gradual cell death during lifetime and the fact that these cells cannot be regenerated may make the cornea lose its transparency and its refractive power, so that a cornea transplant would be the only way to restore the patient's vision. The purpose of corneal specular microscopy is to establish whether the cornea is still functional. In order to obtain a statistically valid diagnosis, a certain number of observations at various locations of the cornea is necessary. The observations

must involve a certain number of endothelium cells. All requests concern the "statistic validation of corneal endothelial cells analysed samples".

3. Request for postponement of the oral proceedings

At the opening of the oral proceedings the appellant requested their postponement, due to serious illness of one of the inventors who wished to attend.

Under Article 15(2) RPBA, "A change of date for oral proceedings may exceptionally be allowed in the Board's discretion following receipt of a written and reasoned request made as far in advance of the appointed date as possible." The notice of the Vice-President of Directorate-General 3 of the European Patent Office dated 16 July 2007 concerning oral proceedings before the boards of appeal of the EPO (Official Journal EPO 2007, Special edition No. 3, 115) explains in more detail how it can be expected that this discretion is exercised. In particular, for a request of a change of date to be allowed the party should advance serious reasons. The request should be filed "as soon as possible after the grounds preventing the party concerned from attending the oral proceedings have arisen". Examples of serious reasons are given under point 2.1 of that notice.

The aim of the above provisions is to fulfil the need for procedural economy while ensuring that the party can be duly represented during the oral proceedings.

The Board notes that the appellant was duly represented by the professional representative of its choice. Article 133(2) EPC specifically requires such a representation for persons not having their residence

or principal place of business in a contracting state to the EPC, who must act through the representative. The attendance of one of the inventors is not relevant for discussion of formal and substantive points in oral proceedings, unless special issues arise, for example in connection with a particular technical point. In the present case, the representative did not put forward any such special issues and the Board cannot see any either. In this context, it is stressed that the above-mentioned notice expressly refers to grounds preventing **the party concerned, i.e. its appointed representative** - not other accompanying persons - from attending.

The Board further notes that although the medical certificate attesting the illness is dated 28 July 2017, the request was only filed four days later, at the last possible point in time, i.e. during the oral proceedings themselves. No reasons were provided why the representative was only informed in the evening of the day before the oral proceedings that the inventor was unable to attend. Hence, it has to be concluded that the request for postponement was not made "as far in advance of the appointed date as possible" within the meaning of Article 15(2) RPBA.

In view of these circumstances, the Board concludes that the need for procedural economy and legal certainty for the public outweighs the present personal wish of one of the inventors to attend, and exercises its discretion not to allow the postponement.

4. Admissibility of the main request

The main request was only filed during the oral proceedings. This constitutes an amendment to the appellant's case, the admission of which is at the

Board's discretion under Article 13(1) and (3) RPBA.

According to Article 13(1) RPBA, "the discretion shall be exercised in view, *inter alia*, of the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy". Moreover, under Article 13(3) RPBA, "Amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board [...] cannot reasonably be expected to deal with without adjournment of the oral proceedings." Another important criterion for assessing the admissibility of amendments to a party's case, according to the established jurisprudence of the boards of appeal, is their *prima-facie* relevance.

The Board notes that the main request was filed at the last possible point in time, without any objective reason for doing so. The outstanding objections to the requests already on file were known by the appellant from the impugned decision and the Board's communication accompanying the summons to oral proceedings. The appellant's argument that an important aspect of the invention had only come to light in a recent discussion with one of the inventors cannot be accepted, as it depends on merely subjective circumstances under the appellant's control.

It is further noted that, compared with the requests already on file, the main request comprises several substantial amendments, including a change in claim category from a process to a device. Hence, the examination of its subject-matter, especially in view of the requirements of Article 123(2) EPC concerning added subject-matter, would entail a relatively high degree of complexity, possibly requiring an adjournment

of the oral proceedings.

Lastly, the amendments are not prima facie relevant, since the steps concerning the determination of a "sample size and calculated relative error", still present in claim 1 of the main request and objected to in the communication accompanying the summons to oral proceedings, remain unclear. The appellant's argument that it was clear that those steps were performed by the claimed microscope is not convincing, since the claim, in one alternative designated "personalized sample", specifically contemplates that "an ideal sampling of said eye corresponding to said corneal endothelial cell analyzed samples is defined by the user".

For these reasons the Board does not admit the main request into the proceedings under Article 13(1) and (3) RPBA.

5. Clarity and sufficiency of disclosure of auxiliary request 2

Claim 1 of auxiliary request 2 is directed to a process for statistic validation of analysed cell samples of corneal endothelial tissue, in other words a process for determining the degree to which the performed analysis of the cell samples could accurately represent the overall conditions of the endothelial tissue of the cornea.

However, the claim does not define in a clear way how this validation should be carried out. The requirements to be fulfilled for acknowledging a certain, desired level of accuracy cannot be derived from the claim wording and the description as a whole.

Steps "a" to "e" define certain inputs to be provided to a software by a user. The inputs relate to a specific analysis of cell samples, either already or yet to be carried out by a corneal specular microscopy device.

Steps "f" and "g" are concerned respectively with the determination of the "statistical power of the sample to be calculated" and of the "sample size and calculated relative error". From the claim wording, in particular also from steps g.1 and g.2, it is not clearly derivable whether these determinations are made by the process or are merely additional inputs to be provided by the user. This is simply not specified.

Steps "h" to "m" are concerned with the presentation of several results of the analysis of the cell samples. In particular, for some "studied variables" a "reliability interval" is displayed (points "F" to "G" of step j). Again, the claim wording does not specify - and hence it remains unclear - whether these reliability intervals are determined by the process itself or are further inputs provided by the user together with, or based on, the analysis of the cell samples.

For these reasons the clarity requirements of Article 84 EPC are not fulfilled.

Assuming that it is the claimed process that performs all those determinations, the basis on which this is done is not derivable from the disclosure of the application as a whole. There are neither general explanations nor specific examples of how the process actually performs the determinations. The Board does not dispute that the terms employed in the claim are

usual terms in ophthalmology or statistics, or that they are clear in their own right. In particular, it accepts that a skilled person knows what a sample size and a relative error are, and how to possibly write an algorithm linking a certain indication of the statistical validity of a sample of cells of the corneal endothelium with certain characteristics of that sample and with a relative error judged acceptable. What the application does not teach is which degree of relative error is considered acceptable by the process and how and which specific characteristics of the sample, for example its size and its more or less even distribution across the corneal endothelium, influence the determinations. Hence Article 83 EPC is not complied with.

As regards the appellant's argument that it was surprising that the application had been refused by the EPO but not in China, Japan and the US, the Board notes that it has to decide on the basis of the provisions of the EPC, which may differ from those of other texts. Decisions of other patent offices, possibly taken on the basis of different claim versions, are in any case not binding on the Board.

In summary, auxiliary request 2 is not allowable.

6. Inventive step of auxiliary request 1

The subject-matter of claim 1 of auxiliary request 1 is a process operatively coupled to a microscope device, for generating several graphics of variables obtained by the microscope device. The generation and display of such graphics for showing the obtained variables, possibly in a user-friendly manner, is directed to the subjective perception of the user and thus constitutes

a presentation of information obtained by that microscope device.

Under Article 52(2)(d) EPC, presentations of information are not regarded as inventions. It follows that the features of the claim relating to presentations of information do not possess a technical character and cannot contribute to an inventive solution to a technical problem (T 641/00, point 6 of the Reasons and T 1543/06, point 2 of the Reasons).

It is the Board's view that the only feature of the claim comprising a technical character is the defined microscope device itself, which, inherently, has to comprise programmable computational means on which software may run.

It has not been disputed that such a microscope device, without the specific software developed by the appellant, belongs to the state of the art. This is clearly acknowledged in the present application (page 4, last paragraph to page 5, fourth paragraph).

Since, as explained above, the other features of the claim do not contribute to inventiveness, the subject-matter of claim 1 of auxiliary request 1 cannot be allowed for lack of inventive step (Article 56 EPC).

The appellant argued that displaying the defined graphics, possibly on a single screen, was a technical feature, because it enhanced the conveying of information to the user. It suffices to note that the expression "convey of information" can only be considered a synonym for "presentation of information", which, as explained, provides no technical character.

Lastly, as explained in point 5 above, whether auxiliary request 1 was allowed in the US has no bearing on the present decision.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. DufRASne

Decision electronically authenticated