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**Datasheet for the decision  
of 1 December 2011**

**Case Number:** T 2196/09 - 3.3.08

**Application Number:** 01970866.8

**Publication Number:** 1319180

**IPC:** G01N 33/487

**Language of the proceedings:** EN

**Title of invention:**

Micro-invasive method for painless detection of analytes in extracellular space

**Applicant:**

Becton, Dickinson and Company

**Headword:**

Optical microprobe system/BECTON, DICKINSON

**Relevant legal provisions:**

EPC Art. 108

EPC R. 99(2)

RPBA Art. 12(4), 13(1)

**Keyword:**

"Admissibility of the appeal (yes)"

"Admissibility of the Main Request and of Auxiliary Requests 1, 3 and 4 (no)"

"Admissibility of Auxiliary Request 2 (yes)"

"Auxiliary Request 2 - added subject-matter (no); clarity (no)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 2196/09 - 3.3.08

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.08  
of 1 December 2011

**Appellant:**  
(Applicant)

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**Representative:**

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**Decision under appeal:**

**Decision of the Examining Division of the  
European Patent Office posted on 8 April 2009  
refusing European patent application  
No. 01970866.8 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman:** M. Wieser  
**Members:** P. Julià  
J. Geschwind

## Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division dated 8 April 2009 whereby the European patent application No. 01 970 866.8, published as International patent application WO 02/25275 (hereinafter "*the application as filed*"), was refused by the examining division.
- II. Basis for the refusal were a Main Request filed on 10 February 2009 and Auxiliary Requests I and II filed on 16 March 2009 at the oral proceedings before the examining division. Claims 1 and 2 of the Main Request read as follows:

"1. An optical microprobe system for detecting at least one analyte in extracellular spaces comprising:

a microprobe body (12) terminating in a distal optical tip (44), the distal optical tip comprising a tapered base portion (305) and a tapered distal tip portion (303) having a tip size less than 20 microns, adapted to enter the stratum corneum of the skin of a subject and extend toward the stratum basale of the skin terminating in extra-cellular spaces containing interstitial fluid, the microprobe body (12) being shaped to cause the microprobe tip to stop in the extra cellular spaces of the skin;

a sensor layer covering the distal optical tip (44) of the microprobe body (12), said sensor layer being adapted to interact with a predetermined analyte to be detected in the interstitial fluid;

an optical detector (42) responsive to interaction of the sensor layer with the predetermined analyte to signal detection of said predetermined analyte."

"2. The system as set forth in claim 1 wherein the microprobe body distal optical tip (44) has a diameter no larger than approximately 10-50 microns."

Claim 1 of the Auxiliary Request I read as claim 1 of the Main Request except for the deletion of the reference signs (12) and (44) and the presence of the additional sentence: "*... wherein a substantial step is provided where the tip portion (303) meets the base portion (305) ...*" after defining the size of the tapered distal tip portion and before the functional features ("*adapted to enter the stratum corneum ...*"). Claim 2 of this request read as claim 2 of the Main Request except for the deletion of the reference sign.

Claim 1 of the Auxiliary Request II read as claim 1 of the Auxiliary Request I except for the introduction, at the very end of the claim, of the sentence: "*... wherein the microprobe body distal optical tip has a diameter no larger than approximately 10-50 microns at its extreme tip*", which essentially corresponded to the subject-matter of claim 2 of both the Main Request and the Auxiliary Request I.

Claim 1 of the Main Request and of Auxiliary Request II were considered not to fulfil the requirements of Article 123(2) EPC. According to the examining division, the features of claim 1 of the Main Request were only disclosed in the specific context of the embodiment described on page 13 of the application as filed. However, this embodiment was defined by other additional features that were not included in the claim. The feature introduced into claim 1 of the Auxiliary

Request II was not disclosed in the application as filed in combination with the other features present in this claim. Claim 1 of the Auxiliary Request I was considered to fulfil the requirements of Article 123(2) EPC but to contravene those of Article 84 EPC because it was unclear whether the feature indicating the tip size referred to its diameter or to its length. Moreover, these claims comprised functional features defining the claimed subject-matter in terms of the result to be achieved but not how the desired effect was actually achieved.

- III. A notice of appeal was filed and, on 17 August 2009, the applicant (appellant) filed a statement setting out its grounds of appeal.
- IV. The examining division did not rectify the contested decision and referred the appeal to the board (Article 109(2) EPC).
- V. On 19 May 2011 and upon request of the board, the appellant filed the enclosures 1 and 2 of its grounds of appeal - the former containing new claims 1 to 11.
- VI. On 22 June 2011, with the summons to oral proceedings, the board sent a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) informing the appellant of its preliminary, non-binding opinion on substantive matters.
- VII. With letter dated 31 October 2011, the appellant replied to the board's communication and filed Auxiliary Requests 1 to 3.

VIII. Oral proceedings were held on 1 December 2011. During these proceedings, the appellant replaced its Auxiliary Request 3 by a new Auxiliary Request 3 and further filed an Auxiliary Request 4.

IX. Claim 1 of the **Main Request** read as claim 1 of the Main Request before the examining decision except for the deletion of the sentence: "... *the distal optical tip comprising a tapered base portion (305) and a tapered distal tip portion (303) ...*" (cf. Section II *supra*).

Claim 1 of the **Auxiliary Request 1** read as claim 1 of the Main Request except that the microprobe body was defined as "... *terminating in a needle shaped distal optical tip having a tip size less than 20 microns adapted ...*" and the presence of the term "and" before the definition of the optical detector.

In both, the Main Request and Auxiliary Request 1, claim 2 read as claim 2 of the Main Request before the examining division (cf. Section II *supra*).

Claim 1 of the **Auxiliary Requests 2 and 3** read as follows:

"1. An optical microprobe system for detecting at least one analyte in extracellular spaces comprising:

    a microprobe body terminating in a needle shaped distal optical tip adapted to enter the stratum corneum of the skin of a subject and extend toward the stratum basale of the skin terminating in extra-cellular spaces containing interstitial fluid, the microprobe body being shaped to cause the microprobe tip to stop in the extra cellular spaces of the skin; wherein the

microprobe body has been fabricated to have a tip size less than 20 microns to enter at the stratum corneum and rest in or proximal of extracellular space of the stratum basale of the epidermis, wherein the microprobe body includes a distal tip portion (303) extending to a base portion (305), and wherein both base portion (305) and tip portion (303) are tapered, with a substantial step where the tip portion (303) meets the base portion (305);

a sensor layer covering the distal optical tip of the microprobe body, said sensor layer being adapted to interact with a predetermined analyte to be detected in the interstitial fluid; and

an optical detector responsive to interaction of the sensor layer with the predetermined analyte to signal detection of said predetermined analyte."

Claim 1 of the **Auxiliary Request 4** read essentially as claim 1 of Auxiliary Request 3 except for the further definition of the substantial step by the sentence "*... and wherein the base portion (305) tapers at approximately four degrees to the step where it meets the tip portion (303) ...*".

Whereas claim 2 of Auxiliary Request 2 read as claim 2 of the Main Request before the examining division (cf. Section II *supra*), this claim was deleted in Auxiliary Requests 3 and 4.

- X. The submissions of the appellant, insofar as they are relevant to the present decision, may be summarized as follows:

*Admissibility of the appeal*

Evidence was on file to show that the statement of grounds of appeal was filed with two enclosures, the first containing new claims 1 to 11. Neither the formalities officer nor the examining division informed the appellant of any deficiencies in its grounds of appeal. It was impossible for the examining division to decide whether or not to rectify its decision without considering new claims 1 to 11. Even without enclosures, the statement of grounds of appeal fulfilled the requirements of Rule 99(2) EPC and Article 12(2) RPBA. It explained the main request in detail and contained the reasons for setting aside the impugned decision. The facts and evidence on which the appeal was based were also clearly indicated in the statement of grounds of appeal.

*Admissibility of the Main Request and of Auxiliary Requests 1 and 2*

During oral proceedings, the time for preparing new requests was short and, in most cases, it was only possible to make small amendments in the claims or to combine them. In the present case, the examining division raised, for the first time, an objection under Article 123(2) EPC at oral proceedings. It was thus necessary to consider the arguments of the examining division and to review the application in order to find a new formulation for the claims. Even the new claims filed were objected by the examining division. As a consequence, there was not enough time at oral proceedings to find a wording for a new set of claims addressing all the objections of the examining division.



The Main Request, filed with the statement of grounds of appeal, was formulated as close as possible to the original claims in order to avoid further objections under Article 123(2) EPC. Auxiliary Requests 1 and 2 were filed in order to address the board's objections raised under Article 123(2) EPC in the communication attached to the summons to oral proceedings and which were not raised in detail at the first instance.

*Auxiliary Request 2*

*Article 123(2) EPC*

Basis for the claimed subject-matter was found on page 13, third paragraph of the application as filed. The fact that different features were cited in a single paragraph did not necessarily mean that they were disclosed only in combination. The skilled person would have understood each sentence of this paragraph as a single feature, describing the microprobe in detail, step by step. The specific values disclosed in this paragraph would not have been understood as obligatory features but only as very special and additional features for a particular embodiment of the microprobe.

*Article 84 EPC*

The application as filed differentiated between "*size*" and "*diameter*" since it was clearly stated "... *under 30 microns in size or diameter*" on page 7, line 8 of the description. Consequently, in the application as filed, "*size*" and "*diameter*" were two different expressions explaining two different parameters of the disclosed microprobe. Thus, the feature "... *have a tip*

*size less than 20 microns ...*" could not refer to the tip diameter but only to its length.

On page 13, lines 9 to 11, the microprobe was described as having a tip size less than 20 microns and on page 14, lines 4 to 5, it was stated that the diameter was of 10-50 microns at its extreme tip. Thus, it was immediately evident to the skilled person that these were two different values concerning two different parameters. By reading the description, in particular the statement made on page 7, line 8, the skilled person would have understood the first value to refer to the tip length (size). Indeed, a tip length of less than 20 microns was essential for entering at the stratum corneum, extending toward, and resting in or proximal of extracellular space of the stratum basale (which on average was found in a depth of less than 20 microns), and stopping before the stratum papillare. The skilled person knew where the microprobe was to be used, namely in those places where the epidermis was known to be on average less than 20 microns.

#### *Admissibility of Auxiliary Requests 3 and 4*

The board's interpretation of the term "or" found on page 7, line 8 of the description as filed, was never put forward by the first instance. It had always been the appellant's conviction that, in the light of the description of the application as filed, the requests on file were clear in the sense of Article 84 EPC and that the board would be convinced by appellant's arguments. The filing of further auxiliary requests would have destroyed appellant's logical argumentation and weaken its position. It made no sense to argue in

one way for some requests and then, for other requests, argue in a different way.

- XI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 11 of its Main Request or, in the alternative, on the basis of the First or Second Auxiliary Requests filed with letter of 31 October 2011, or the Third or Fourth Auxiliary Requests as filed during the oral proceedings.

## **Reasons for the Decision**

### *Admissibility of the appeal*

1. The main request is described in detail on page 2, point 2.1 of the appellant's statement of grounds of appeal, with explanation of the amendments introduced in this request in comparison to the published claims. In particular, when reading the appellant's grounds of appeal, the amendments introduced into independent claim 1 are straightforward and, although not all features introduced into the other independent claims of the main request (claim 8) are derivable from the grounds of appeal, the facts and reasons on which the appellant relies for its request to set aside the decision under appeal are certainly explained in, and directly derivable from, the appellant's statement of grounds of appeal.
  
2. In view of the above, the board does not deem it necessary to consider whether the evidence filed by the appellant supports its assertion that the enclosures of

its statement of grounds of appeal, in particular enclosure 1 containing new claims 1 to 11, were indeed filed with these grounds of appeal. The board is satisfied that the appellant's statement of grounds of appeal, even without enclosures, sets out in a sufficiently clear manner the basis for the appellant's request to set aside the decision under appeal and deals adequately with the reasoning of the examining division in that decision.

3. Thus, the appeal is admissible (Article 108 EPC and Rule 99(2) EPC).

*Admissibility of the Main Request and of Auxiliary Requests 1*

4. According to the established case law of the Boards of Appeal, the function of appeal proceedings is to give a decision upon the correctness of a separate earlier decision taken by a department of first instance (cf. "Case Law of the Boards of Appeal of the EPO", 6th edition 2010, VII.E.1, page 821). In line therewith, Article 12(4) RPBA states that it is within the power of the board to hold inadmissible facts, evidence or requests which could have been admitted in the first instance. Although new requests with amended claims may exceptionally be admitted in appeal proceedings, it is not the purpose of the appeal to give the appellant the opportunity to recast its claims as it sees fit and to have all its requests admitted into these proceedings (cf. "Case Law", *supra*, VII.E.16.1.2, page 889).

5. As for the Main Request and Auxiliary Request 1, the board has the following considerations:
  - 5.1 The Main Request dealt with by the examining division in the decision under appeal comprised a technical feature characterizing the distal optical tip ("*... comprising a tapered portion (305) and a tapered distal tip portion (303) ...*") which was further defined in more detail in Auxiliary Requests I and II before the examining decision ("*... wherein a substantial step is provided where the tip portion meets the base portion ...*") (cf. Section II *supra*). None of these features are present in the Main Request and the Auxiliary Request 1 filed in appeal proceedings (cf. Section IX *supra*). The deletion of these features in appeal proceedings does not address, let alone overcome, the objections raised by the examining division and reverts the claimed subject-matter to that examined at a much earlier stage of the examination proceedings. Indeed, the claims of the Main Request and of the Auxiliary Request 1 in appeal proceedings are, as argued by the appellant itself (cf. Section X *supra*), closer to those originally filed than those underlying the decision under appeal.
  - 5.2 According to the "Minutes of the oral proceedings before the examining division", Auxiliary Request II was filed at the oral proceedings before the examining division after the applicant requested, and was granted, a short break. After examining this Auxiliary Request II and considering it not to meet the requirements of Article 123(2) EPC, the applicant was asked whether it had further requests, to which it replied that it did not wish to introduce a new request

(cf. pages 2 and 3 of the "Minutes of the oral proceedings before the examining division"). Thus, supplementary time was offered by the examining division and not availed by the applicant because it did not consider necessary or, as stated in the Minutes, it did not wish to file further requests. Indeed, in the light of the nature and type of amendments introduced into the Main Request and the Auxiliary Request 1 in appeal proceedings, the board considers that it was not a lack of opportunity or of time for the applicant to file such requests at the oral proceedings before the examining division but that it had good reasons not to file them at that stage of the examination proceedings since they would certainly not have been admitted into the proceedings by the examining division.

- 5.3 Thus, neither the Main Request nor the Auxiliary Request 1 are in line with the purpose of appeal proceedings as established in the case law. Therefore, in accordance with Article 12(4) RPBA, the board, exercising its discretion, decides not to admit these requests into the appeal proceedings.

#### *Auxiliary Request 2*

#### *Admissibility of the Auxiliary Request 2*

6. The subject-matter of this request corresponds essentially to that of the requests dealt with by the examining division in the decision under appeal, in particular to that of Auxiliary Request I, which was considered by the examining division to fulfil the requirements of Article 123(2) EPC but not those of Article 84 EPC (cf. Sections II and IX *supra*). Thus,

Auxiliary Request 2 is admitted into the appeal proceedings.

*Article 123(2) EPC*

7. The subject-matter of Auxiliary Request 2 is directed to the second preferred embodiment disclosed in the application, namely the microprobe shown in Figure 8 and described in detail on page 13, third paragraph of the application as filed. This paragraph refers to several features that characterize this embodiment. In the board's view, it is directly derivable from the information given therein that a certain degree of generalization is allowable for some of these features. In particular, it is stated that the "*(b)ase portion 305 ... tapers at **approximately** four degrees to the step where it meets the tip portion 303*" (cf. page 13, lines 15 to 17 of the application as filed) (bold letters by the board). Other features, such as the width and length of the base portion 305 (5.1068 mm and 9.5791 mm, respectively), are also characterized by such very specific values that the skilled person would immediately understand them to be only preferred values and not essential, fixed values of these features.
  
8. Although in the above referred to paragraph, there is no mention of the distal optical tip being "*needle shaped*", this feature - introduced in Auxiliary Request 2 - describes, however, the tip portion in the block diagrams of Figures 2 and 7 of the application as filed (cf. page 6, lines 22 to 23 and page 12, lines 5 to 6, respectively). In the specific embodiments shown in Figures 1, 3 to 6 as well as in Figure 8, the tip portion is also needle shaped. Therefore, this feature

is considered to be an essential feature directly and unambiguously derivable from the application as filed, even though in an implicit manner.

9. Thus, the subject-matter of Auxiliary Request 2 fulfils the requirements of Article 123(2) EPC.

*Article 84 EPC*

10. In Auxiliary Request 2, it is stated that "... *the microprobe body has been fabricated to have a **tip size less than 20 microns** to enter at the stratum corneum ...*" (cf. Section IX *supra*). The actual meaning of the feature indicated in bold characters by the board is contentious, the appellant interpreting "**size**" as referring to the tip length and not to its diameter as done by the examining division in the decision under appeal (cf. pages 4 and 5, point 2.2 of the decision under appeal).

- 10.1 The same wording as in Auxiliary Request 2 is also found on page 13, line 11 to 17 of the application as filed, wherein it is stated that the "... *microprobe 301 shown in Fig. 8 ... has been fabricated to have a tip size less than 20 microns ...*". This microprobe is further described as including a (tapered) "*distal tip portion 303*" **extending** proximally 9.8914 mm to a (tapered) "*base portion 305*", which itself has a **length** of 9.5791 mm (cf. page 13, lines 13 to 17). In view of these specific measures, the board considers that the reference found in that paragraph to "... *a tip size less than 20 microns ...*" cannot be interpreted as defining the length of the (distal) tip. The less so, because in the immediately following paragraph, where



the manufacture of the microprobe is described in detail, reference is made to the tip being "... *pulled so that the fiber tapers from 600 microns down to 10-50 microns at its extreme tip ...*", wherein the 600 microns and 10-50 microns are clearly identified in that paragraph as referring to the **diameter** of the tip (cf. page 13, line 23 to page 14, line 5).

10.2 The board is convinced that, when reading this description of the second embodiment on pages 13 and 14 of the application as filed, the skilled person would immediately understand the reference to the tip size as defining the diameter of the tip and not its length. This interpretation is not in contradiction with the sentence found on page 7 of the application as filed and referred to by the appellant (cf. Section X *supra*). This sentence describes the integrated sensor head 14 (Figure 3) of the first embodiment of the application as filed (Figure 1) and reads "... *is preferably a small device on the order of under 30 microns in size or diameter ...*" (cf. page 7, lines 7 to 8). Contrary to the appellant's interpretation, the board does not understand the term "or" in that sentence as introducing two different alternatives. This term is used in that sentence to further clarify or enlighten the term "*size*", i.e. by defining "*size*" as actually being "*diameter*".

10.3 This interpretation is also more realistic and technically meaningful than that of the appellant. Attachment 1 or enclosure 2 of the appellant's statement of grounds of appeal shows the structure of the (human) skin and defines the epidermis as a layer of 30-2000  $\mu\text{m}$  (microns), starting with the stratum

disjunctum and stratum corneum and ending with the stratum basale which is close to the stratum papillare of the dermis. A tip length of less than 20 microns may well "*enter at the stratum corneum*" but, with such a short length, it may not be able to reach and "*rest in or proximal of the extracellular space of the stratum basale of the epidermis*" as required in Auxiliary Request 2 (cf. Section IX *supra*). There is no evidence on file from which it can be deduced, firstly, that certain regions of the human body have an epidermis layer of a depth less than 20 microns and, secondly, how to find these regions. In any case, a limitation in this respect is not present in the claims of Auxiliary Request 2. It is worth noting here that the relevance of a small diameter size for the tip is also directly derivable from the application as filed which states that the extremely small size of the tip allows its insertion "... **through** gaps in between most cells or **through** the membrane of a cell without, damaging the cell ..." (in bold by the board) (cf. page 8, lines 1 to 3).

- 10.4 It follows from the above that, both from the application as filed itself and from a sensible technical evaluation of the claimed subject-matter, the sentence "*a tip size less than 20 microns*" in claim 1 of Auxiliary Request 2 is to be understood as referring to the diameter of the tip. In view of this interpretation, the subject-matter of claim 2 of Auxiliary Request 2, which defines the distal optical tip as having "*a diameter no larger than approximately 10-50 microns*", is at best ambiguous or, at worst, totally inconsistent. Therefore, Auxiliary Request 2 is

considered not to meet the requirements of clarity and conciseness of Article 84 EPC.

11. In view of the above conclusion, the board does not consider it necessary to further examine and assess the objection raised by the examining division in the decision under appeal against the presence of functional features in the claimed subject-matter (cf. page 5, point 2.3 of the decision under appeal).

*Admissibility of Auxiliary Requests 3 and 4*

12. Auxiliary Request 3 and 4 were filed at the oral proceedings before the board when it announced its opinion on Auxiliary Request 2. These auxiliary requests represent an amendment to the appellant's case and therefore, in addition to Article 12(4) EPC (cf. point 4 *supra*), Article 13(1) RPBA is also of relevance for assessing whether or not to admit them into the appeal proceedings.

- 12.1 An objection under Article 84 EPC concerning the feature "*a tip size less than 20 microns*" was already raised in the first instance procedure. The reasons why this feature was found not to be allowable were clearly explained in the decision under appeal (cf. pages 4 and 5, point 2.2 of the decision under appeal). A similar reasoning was also put forward in detail by the board in its communication pursuant to Article 15(1) RPBA (cf. Section VI *supra*; pages 8 to 10, point 19 of the board's communication). This objection could thus hardly come as a surprise to the appellant. However, neither the appellant's Main Request filed with the statement of grounds of appeal nor any of the Auxiliary

Requests filed in reply to the board's communication did address, let alone overcome, this specific objection which is addressed only now by Auxiliary Requests 3 and 4. The amendment introduced into these requests for overcoming this objection, namely the deletion of a dependent claim, is straightforward and clear. However, in the board's view, requests comprising such an amendment could well have been filed at the first instance proceedings (Article 12(4) RPBA).

- 12.2 The board cannot accept appellant's argument that the filing of auxiliary requests would have weakened its position and would have run against its logical argumentation (cf. Section X *supra*). Indeed, already at first instance, the appellant did actually file an auxiliary request (Auxiliary Request II; cf. Section II *supra*) which intended to address this objection under Article 84 EPC, even though it was considered not to overcome the objection by the examining division. It is not evident why a request comprising the amendment introduced now in Auxiliary Requests 3 and 4 was not already filed at an earlier stage of the proceedings. It is not up to the board to judge upon the appellant's procedural strategy but only to decide upon the merits of its claim requests. The reasons given and the conclusions arrived at for one request do not necessarily need to be of relevance for other requests. Should appellant's argument be taken at face value *arguendo*, it would imply that, for whatever objection raised under the EPC, no auxiliary claim requests could ever be filed since it would be understood as an admission of the objection's relevance and thereby, in the appellant's view, the position of an applicant and/or a patent proprietor would be immediately

weakened. This is certainly not in line with the normal course of proceedings before, and the normal practice of, the EPO and the boards of appeal.

- 12.3 According to Article 13(1) RPBA amendments to a party's case after it has filed its grounds of appeal may be admitted and considered at the board's discretion. This discretion shall be exercised in view of *inter alia* the current state of the proceedings, the complexity of the new subject matter submitted and the need for procedural economy.

Oral proceedings in appeal are usually, if not always, the latest stage of appeal proceedings and thus, requests submitted at that stage are usually considered to be late. In the present case, and in view of the appellant's interpretation of claim 1 and of the objections raised during the proceedings at first instance (cf. point 11 *supra*), a cursory assessment of Auxiliary Requests 3 and 4 suggests that a complete substantive examination under Article 84 EPC would have to be performed. Similarly, a complete examination under Articles 54 and 56 EPC, for which in the decision under appeal observations have been made only in obiter dicta, might also be required. The question might also arise whether or not to remit the case to the first instance department for further prosecution. None of these considerations speaks for procedural economy but only adds to the complexity of the case.

13. Thus, the board, in the exercise of its discretion under Article 13(1) RPBA, decides not to admit Auxiliary Requests 3 and 4 into the appeal proceedings.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

A. Wolinski

M. Wieser