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Datasheet for the decision of 11 September 2014

Case Number: T 0730/10 - 3.3.02

Application Number: 95918980.4

Publication Number: 0758401

IPC: G01N33/86

Language of the proceedings: EN

Title of invention:
DRY PROTHROMBIN TIME ASSAY

Patent Proprietor:
Beckman Coulter, Inc.

Opponents:
Alere San Diego, Inc.
Roche Diagnostics GmbH

Headword:
Assay/BECKMAN COULTER

Relevant legal provisions:
EPC Art. 113(1), 123(2)
RPBA Art. 13(1)

Keyword:
Substantial procedural violation - (no)
Main request and auxiliary request 2 - added subject-matter (yes)
Admissibility of auxiliary requests 1 and 3 filed at the oral proceedings (no)

Decisions cited:
T 0268/00, T 1993/07, T 1898/11, T 2044/09

Catchword:

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Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0730/10 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 11 September 2014

Appellant: (Patent Proprietor)	Beckman Coulter, Inc. 250 S. Kraemer Boulevard Brea, CA 92821 (US)
Representative:	Boult Wade Tennant Verulam Gardens 70 Gray's Inn Road London WC1X 8BT (GB)
Respondent: (Opponent 1)	Alere San Diego, Inc. 9975 Summers Ridge Road San Diego CA 92121 (US)
Representative:	Broughton, Jon Philip Broughton IP 1 Alfred Place London WC1E 7EB (GB)
Respondent: (Opponent 3)	Roche Diagnostics GmbH Sandhoferstr. 116 68305 Mannheim (DE)
Representative:	Weiss, Wolfgang Weickmann & Weickmann Patentanwälte Postfach 86 08 20 81635 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 2 February 2010 revoking European patent No. 0758401 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	U. Oswald
Members:	K. Giebeler
	R. Cramer

Summary of Facts and Submissions

I. European patent No. 0 758 401, based on European patent application No. 95918980.4 (published as WO95/30770) and entitled "Dry prothrombin time assay", was granted with 12 claims.

II. Claims 1 and 7 of the application as filed read:

"1. A test article for performing dry reagent prothrombin time assays, said test article comprising

a solid phase matrix;

dry thromboplastin immobilized on or within the solid phase matrix, wherein the thromboplastin is substantially free from substances found in thromboplastin purified from brain extract which cause aberrant functioning intermediate transition states as the thromboplastin is rehydrated with liquid sample; and coagulation neutral agents which facilitate rehydration of the thromboplastin upon contact of the solid phase matrix with the liquid sample."

"7. An improved prothrombin time assay of the type wherein a blood or plasma sample is applied to a solid phase matrix to contact dry thromboplastin to initiate a detectable reaction, wherein the improvement comprises providing a coagulation neutral agent within the matrix and contacting a dry thromboplastin which is substantially free from substances found in thromboplastin purified from brain extract which cause aberrant functioning transition states as the thromboplastin is rehydrated with the sample."

III. Claims 1 and 6 as granted read:

"1. A test article for performing dry reagent prothrombin time assays, said test article comprising:

a solid phase matrix;

dry purified recombinant thromboplastin immobilized on or within the solid phase matrix, wherein the thromboplastin is free from substances found in thromboplastin purified from brain extract which cause aberrant functioning intermediate transition states as the thromboplastin is rehydrated with liquid sample; and

one or more coagulation neutral agents which facilitate rehydration of the thromboplastin upon contact of the solid phase matrix with the liquid sample, wherein the solid phase matrix is a bibulous or non-bibulous structure, and wherein the bibulous structure is a porous membrane structure composed of a hydrophilic and non-swellable polymeric matrix material having pore dimensions which permit entry of blood plasma and proteins while excluding blood cells; and wherein the non-bibulous structure is an impermeable structure having at least one discrete capillary flow path."

"6. An improved prothrombin time assay of the type wherein a blood or plasma sample is applied to a solid phase matrix to contact dry purified thromboplastin to initiate a detectable reaction, wherein the improvement comprises providing one or more coagulation neutral agents within the matrix and contacting said dry purified thromboplastin which is recombinant thromboplastin and is free from substances found in thromboplastin purified from brain extract which cause aberrant functioning transition states as the thromboplastin is rehydrated with the sample, wherein the solid phase matrix is a bibulous or non-bibulous structure, and wherein the bibulous structure is a

porous membrane structure composed of a hydrophilic and non-swellable polymeric matrix material having pore dimensions which permit entry of blood plasma and proteins while excluding blood cells; and wherein the non-bibulous structure is an impermeable structure having at least one discrete capillary flow path."

IV. The patent was opposed by three parties. The grounds for opposition were lack of novelty and inventive step (Article 100(a) EPC), insufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC). Opponent 2 withdrew its opposition before the opposition division took its decision.

V. The opposition division decided that the claimed invention of the main request before it complied with Article 123(2) EPC, but did not fulfil the requirement of sufficiency of disclosure (Articles 83 and 100(b) EPC), and that the claims of the first auxiliary request met the requirements of Rules 80 and 116 EPC and Article 123(2) EPC, but failed to comply with Article 123(3) EPC. It therefore revoked the patent.

VI. The patent proprietor (hereafter appellant) filed an appeal against the decision of the opposition division. With the grounds of appeal, the appellant submitted the main request and first auxiliary request on which the opposition division had based its decision.

VII. Opponents 1 and 3 (hereafter respondents 1 and 3) responded to the appeal.

VIII. The board summoned the parties to oral proceedings and expressed its preliminary opinion in a communication.

IX. Oral proceedings were held on 11 September 2014.

During the oral proceedings, the appellant submitted a new first auxiliary request (hereafter auxiliary request 1), maintained the first auxiliary request filed with the grounds of appeal (hereafter auxiliary request 2), and submitted a new second auxiliary request (hereafter auxiliary request 3).

X. Independent claims 1 and 6 of the **main request** are identical to the respective claims as granted.

XI. Claims 1 and 6 of **auxiliary request 1** read:

"1. A test article for performing dry reagent prothrombin time assays, said test article comprising:

a solid phase matrix;

dry purified recombinant thromboplastin immobilized on or within the solid phase matrix, wherein the thromboplastin is free from substances found in thromboplastin purified from brain extract which cause aberrant functioning intermediate transition states as the thromboplastin is rehydrated with liquid sample; and

coagulation neutral agents which facilitate rehydration of the thromboplastin upon contact of the solid phase matrix with the liquid sample, wherein the solid phase matrix is a bibulous or non-bibulous structure, and wherein the bibulous structure is a porous membrane structure composed of a hydrophilic and non-swellable polymeric matrix material having pore dimensions which permit entry of blood plasma and proteins while excluding blood cells; and wherein the non-bibulous structure is an impermeable structure having discrete capillary flow paths."

"6. An improved prothrombin time assay of the type wherein a blood or plasma sample is applied to a solid phase matrix to contact dry purified thromboplastin to initiate a detectable reaction, wherein the improvement comprises providing a coagulation neutral agent within the matrix and contacting said dry purified thromboplastin which is recombinant thromboplastin and is free from substances found in thromboplastin purified from brain extract which cause aberrant functioning transition states as the thromboplastin is rehydrated with the sample, wherein the solid phase matrix is a bibulous or non-bibulous structure, and wherein the bibulous structure is a porous membrane structure composed of a hydrophilic and non-swellable polymeric matrix material having pore dimensions which permit entry of blood plasma and proteins while excluding blood cells; and wherein the non-bibulous structure is an impermeable structure having discrete capillary flow paths."

XII. Claims 1 and 6 of **auxiliary request 2** read:

"1. A test article for performing dry reagent prothrombin time assays, said test article comprising:

a solid phase matrix;

dry purified recombinant thromboplastin immobilized on or within the solid phase matrix, wherein said thromboplastin consists of purified recombinant tissue factor protein and a purified artificial lipid population; and

one or more coagulation neutral agents which facilitate rehydration of the thromboplastin upon contact of the solid phase matrix with the liquid sample, wherein the solid phase matrix is a bibulous or non-bibulous structure, and wherein the bibulous structure is a porous membrane structure composed of a

hydrophilic and non-swellable polymeric matrix material having pore dimensions which permit entry of blood plasma and proteins while excluding blood cells; and wherein the non-bibulous structure is an impermeable structure having at least one discrete capillary flow path."

"6. An improved prothrombin time assay of the type wherein a blood or plasma sample is applied to a solid phase matrix to contact dry purified thromboplastin to initiate a detectable reaction, wherein the improvement comprises providing one or more coagulation neutral agents within the matrix and contacting said dry purified thromboplastin which is a recombinant thromboplastin consisting of purified recombinant tissue factor protein and a purified artificial lipid population, wherein the solid phase matrix is a bibulous or non-bibulous structure, and wherein the bibulous structure is a porous membrane structure composed of a hydrophilic and non-swellable polymeric matrix material having pore dimensions which permit entry of blood plasma and proteins while excluding blood cells; and wherein the non-bibulous structure is an impermeable structure having at least one discrete capillary flow path."

XIII. The sole claim of **auxiliary request 3** reads:

"1. An improved prothrombin time assay of the type wherein a blood or plasma sample is applied to a solid phase matrix to contact dry purified thromboplastin to initiate a detectable reaction, wherein the improvement comprises providing a coagulation neutral agent within the matrix and contacting said dry purified thromboplastin which is recombinant thromboplastin and is free from substances found in thromboplastin

purified from brain extract which cause aberrant functioning transition states as the thromboplastin is rehydrated with the sample, wherein the solid phase matrix is a non-bibulous structure, and wherein non-bibulous structures are impermeable structures having discrete capillary flow paths."

XIV. The appellant's arguments, insofar as they are relevant for the present decision, can be summarised as follows:

Substantial procedural violation

The opposition division had committed a substantial procedural violation by basing its decision concerning sufficiency of disclosure on factual reasoning on which the appellant had had no opportunity to comment. This concerned the opposition division's position, expressed for the first time in its written decision, that since the delta PT value for Innovin™ decreased from 50 in the liquid assay of Figure 1 to 38 in the dry reagent assay of Figure 3 of the patent in suit, it had to be concluded that Innovin™ contained disturbing intermediate thromboplastin transition state substances. This evaluation of the figures had never been discussed before and had thus come as a complete surprise to the appellant.

Main request and auxiliary request 2 - Article 123(2) EPC

Claim 1 complied with Article 123(2) EPC. The feature "one or more coagulation neutral agents" in the context of claim 1 was based on page 11, lines 36-37 and claims 1 and 7 of the application as filed. The feature "having at least one discrete capillary flow path" in the context of claim 1 was based on page 11, line 33 to

page 12, line 2 of the application as filed. Since the sentence starting on line 33 of page 11 referred to non-bibulous structures in the plural, grammatically the flow paths had to be in the plural, too. Said sentence referred to a singular sample, and the use of a single flow path for a single sample was known from documents US 5,110,727 (hereafter D1) and US 4,756,884 (hereafter D9). Therefore, the skilled person would derive the use of a single flow path for a single sample from the application as filed in combination with common general knowledge.

Admissibility of late-filed auxiliary requests 1 and 3

The amendments in auxiliary requests 1 and 3 dealt with the objections raised, were clearly allowable and did not raise new issues. Therefore, these requests should be admitted into the proceedings.

XV. The respondents' arguments, insofar as they are relevant for the present decision, can be summarised as follows:

Substantial procedural violation

The opposition division had not committed a substantial procedural violation since its decision was based on grounds and evidence which had been debated between the parties. By evaluating the results of Figures 1 and 3 of the patent is suit with respect to Innovin™, the opposition division had merely expanded the point that the test of paragraph [0037] of the patent in suit was insufficient; this could at best be seen as a new argument.

Main request and auxiliary request 2 - Article 123(2) EPC

Claim 1 did not comply with Article 123(2) EPC since there was no basis in the application as filed for the claimed test article comprising only one coagulation neutral agent and only one discrete capillary flow path.

Admissibility of late-filed auxiliary requests 1 and 3

Auxiliary requests 1 and 3 should not be admitted into the proceedings since they had been filed extremely late and were not allowable under Article 123(2) EPC. Moreover, auxiliary request 3 was not allowable under Articles 84 and 123(3) EPC and Rule 80 EPC, and raised complex new issues.

XVI. The final requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution because of an alleged procedural violation, or that the case be remitted to the opposition division for further prosecution on the basis of the main request filed with the statement of grounds of appeal, or on the basis of the first auxiliary request filed at the oral proceedings (hereafter auxiliary request 1), or on the basis of the first auxiliary request filed with the statement of grounds of appeal (hereafter auxiliary request 2), or on the basis of the second auxiliary request filed at the oral proceedings (hereafter auxiliary request 3). The appellant furthermore requested that the appeal fee be refunded.

The respondents requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Alleged substantial procedural violation

2.1 The appellant considered that its right to be heard had been violated, on the basis that the factual reasoning for refusing the main request for lack of sufficiency of disclosure, as given by the opposition division in its written decision, was different from that presented by the opponents, and that it had had no opportunity to comment on the opposition division's analysis based on Figures 1 and 3 of the patent in suit that had led it to conclude that the recombinant thromboplastin Innovin™ contained disturbing intermediate transition state substances.

2.2 According to Article 113(1) EPC, a decision by the EPO can only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments.

It is the consistent case law of the Boards of Appeal that the "grounds and evidence" under Article 113(1) EPC are to be understood as meaning the essential legal and factual reasoning on which the EPO has based its decision. The right to be heard pursuant to Article 113(1) EPC only disqualifies fresh grounds or evidence as a new basis for taking a decision, while the use of a fresh argument in a decision still based on grounds communicated beforehand is not precluded (T 1898/11 of 27 July 2012; T 0268/00 of 16 December 2003).

2.2.1 In point II-2.2 of the decision under appeal, the opposition division sets out the reasons as to why it considered that the main request did not fulfill the requirement of sufficiency of disclosure, which can be summarised as follows:

The opposition division starts with the assumption that in order for the claimed subject-matter to be sufficiently disclosed, the skilled person had to be able to identify with a suitable test whether the functional feature "is free from substances found in thromboplastin purified from brain extract which cause aberrant functioning intermediate transition states as the thromboplastin is rehydrated with liquid sample" in claim 1 would apply to a purified recombinant thromboplastin; such a functional test was not known from the prior art, but was provided in paragraph [0037] of the patent in suit. According to said test, the performance of a thromboplastin sample is first characterised in a liquid phase prothrombin time test and then in a dry reagent prothrombin time assay, which may contain one or more additional coagulation neutral agents; the thromboplastin sample is considered to contain aberrant functioning intermediate thrombo-plastin transition state substances if the ability of the dry reagent assay to discriminate between samples of differing prothrombin times is impaired relative to the liquid phase prothrombin time assay. The opposition division notes that the exact nature of the dry reagent prothrombin time assay was not specified in paragraph [0037] and therefore doubts that a consistent result could be achieved with the test; a skilled person confronted with a different result would not know whether this was due to a difference in the nature of

the assay or to the presence of disturbing intermediate transition state substances.

The opposition division further considers that the dry reagent assay used in the test according to paragraph [0037] could be the simplified dry reagent assay of Example 2 of the patent in suit, and compares the results of the liquid phase prothrombin time assay shown in Figure 1 with those of the simplified dry reagent assay shown in Figure 3 of the patent in suit. The opposition division observes that the same prothrombin time values are obtained for the thromboplastin preparations derived from brain, whereas that for the recombinant thromboplastin Innovin™ was decreased. In view of paragraph [0037] of the patent in suit, these results would lead to the conclusion that Innovin™ contained disturbing intermediate transition state substances and the thromboplastin preparations derived from brain did not, which was however contrary to the proprietor's assertions.

The opposition division concludes that the functional test described in paragraph [0037] of the patent in suit did not lead the skilled person to draw specific conclusions concerning the presence of disturbing intermediate transition state substances, and that, in the absence of other tests in the prior art or in the patent in suit, the claimed invention lacked sufficiency of disclosure.

2.2.2 Having regard to the minutes of the oral proceedings held before the opposition division (see in particular page 3) and to point 3.5.1 of the notice of opposition filed by respondent 3, it is apparent that respondent 3 had argued that the claimed subject-matter lacked sufficiency of disclosure, because the patent in suit

did not provide any teaching as to how the presence or absence of the aberrant functioning intermediate transition state substances referred to in the claims could be determined, and that the test described in paragraph [0037] of the patent in suit did not allow this determination. According to page 3, paragraph 1 of the minutes, respondent 3 submitted that said test did not require the presence of coagulation neutral agents or a matrix and that such a test was described in Example 2 of the patent in suit. This example showed that such a test did not determine the presence or absence of the substances in question; the impurities in thromboplastin from brain extract did not lead to the formation of intermediate transition state substances in the dry assay, because the same prothrombin time values were obtained in Figure 1 (liquid assay) and Figure 3 (dry assay).

From point 7 of said minutes, it is apparent that the appellant responded to these submissions and argued that the skilled person would know which test to apply and that the reference to Example 2 and Figure 3 was misleading and not encompassed by the scope of the claim; Figure 1 (liquid assay) and Figure 3 (simplified liquid assay) referred to different assays and could not be compared.

2.3 In view of the above, the board considers that the essential legal and factual reasoning on which the opposition division based its decision concerning sufficiency of disclosure was that (i) a functional test to determine the functional feature concerning aberrant functioning intermediate thromboplastin transition state substances was a prerequisite to enable the skilled person to carry out the claimed invention, (ii) paragraph [0037] of the patent in suit

provided the only functional test, (iii) this functional test could not provide consistent results, and (iv) a comparison between the results of Figures 1 and 3 confirmed that said test led to contradictory results. The board is convinced that the appellant had an opportunity to present its comments on this essential legal and factual reasoning which had been brought forward by the respondents and discussed at the oral proceedings before the first instance.

With respect to point (iv), the respondents' submission only addressed the allegedly contradictory results concerning the thromboplastin preparations derived from brain extract, whereas the opposition division's analysis additionally included results concerning the recombinant thromboplastin preparation Innovin™. The board takes the position that this additional point raised by the opposition division for the first time in its written decision represents merely an argument and does not change the essential legal and factual reasoning, which had been brought forward beforehand and on which the appellant had had an opportunity to comment.

2.4 In conclusion, the board considers that the opposition division did not commit a substantial procedural violation. Therefore, there is no reason for an immediate remittal of the case to the opposition division for further prosecution (Article 11 RPBA). Furthermore, the request for reimbursement of the appeal fee (Rule 103(1)(a) EPC) is refused.

3. Added subject-matter (Article 123(2) EPC)

3.1 Main request

3.1.1 Claim 1 refers to a test article comprising "a solid phase matrix", which "is a bibulous or non-bibulous structure", and "wherein the non-bibulous structure is an impermeable structure having at least one discrete capillary flow path". The test article according to claim 1 furthermore comprises "one or more coagulation neutral agents".

3.1.2 Article 123(2) EPC stipulates that a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. It is the established case law of the Boards of Appeal that the content of an application comprises the disclosure directly and unambiguously derivable from it.

3.1.3 The only passage in the application as filed which refers to capillary flow paths is in the paragraph bridging pages 11 and 12, which states: "Non-bibulous structures will typically be impermeable structures having discrete capillary flow paths therein for receiving the blood or plasma sample being tested. The dry thromboplastin and optionally coagulation neutral agent(s) will be coated on the wall(s) of the capillary flow paths so that the thromboplastin will be rehydrated as sample is drawn therethrough by capillary action".

There is thus no explicit disclosure in the application as filed of a non-bibulous structure being an impermeable structure having one discrete capillary flow path. Hence the question arises whether the skilled person would still derive the claimed subject-matter directly and unambiguously from the application as filed.

The appellant has submitted that the reference to flow paths in the plural in the sentence starting in line 33 of page 11 of the application as filed was merely a grammatical consequence of the reference to non-bibulous structures in the plural, and has pointed out that said sentence referred to a singular sample. According to the appellant, the skilled person would derive the use of a single flow path for a single sample from the application as filed in combination with common general knowledge, because the use of a single flow path for a single sample was known from the prior art documents D1 and D9.

The board cannot follow this line of argument. Firstly, documents D1 and D9 are patent documents and do not form part of common general knowledge. Secondly, the board considers that even if it was assumed that the skilled person knew from common general knowledge that it was possible to use a single flow path for a single sample, that would not imply a clear and unambiguous disclosure in the application as filed of the presence of a single flow path in the claimed test article. According to the consistent case law of the Boards of Appeal, the implicit disclosure of a document such as the application as filed and underlying the patent in suit means no more than the clear and unambiguous consequence of what is explicitly mentioned. Whilst common general knowledge must be taken into account in deciding what is clearly and unambiguously implied by the explicit disclosure, the question of what may be rendered obvious by that disclosure in the light of common general knowledge is not relevant to the assessment of what is implied by said disclosure.

Therefore, the application as filed does not disclose a test article according to claim 1 comprising one discrete capillary flow path.

3.1.4 Concerning the feature "one or more coagulation neutral agents" in the context of claim 1, the board notes that claim 1 of the application as filed refers to "coagulation neutral agents" only in the plural form. Thus the question arises whether there is a basis in the application as filed for the test article of claim 1 comprising only a single coagulation neutral agent.

Page 11, lines 36-37 of the application as filed refers to "coagulation neutral agent(s)" only in the context of non-bibulous structures having discrete capillary flow paths. However, claim 1 explicitly states that the solid phase matrix is a bibulous or non-bibulous structure, and there is no direct and unambiguous disclosure in said passage on page 11 of the claimed test article comprising a single coagulation neutral agent in combination with a bibulous structure.

Furthermore, claim 7 of the application as filed relates to a prothrombin time assay which comprises providing a coagulation neutral agent within the matrix. However, claim 1 does not require that the coagulation neutral agent is within the matrix, and claim 7 of the application as filed therefore cannot serve as a basis for the presence of a single coagulation neutral agent in the context of claim 1.

The board concludes that the application as filed does not disclose a test article according to claim 1 comprising only one coagulation neutral agent.

3.1.5 Consequently, claim 1 of the main request does not comply with Article 123(2) EPC.

3.2 Auxiliary request 2

Claim 1 of auxiliary request 2 refers to "one or more" coagulation neutral agents, and to a solid phase matrix which is a bibulous or non-bibulous structure and wherein the non-bibulous structure is an impermeable structure having "at least one" discrete capillary flow path, as does claim 1 of the main request.

Consequently, auxiliary request 1 is not allowable under Article 123(2) EPC for the same reasons as set out above for the main request. It is thus not necessary for the board to express its position on whether or not auxiliary request 2 complies with Article 123(3) EPC.

4. Admissibility of auxiliary requests 1 and 3

4.1 The admission of late filed requests in appeal proceedings is governed by the Rules of Procedure of the Boards of Appeal (RPBA). According to Article 12(2) RPBA, the statement of grounds of appeal and the reply shall contain a party's complete case. Article 13(1) RPBA leaves it to the board's discretion to admit any amendment to a party's case after it has filed its grounds of appeal. This discretion is to be exercised in view of *inter alia* the complexity of the new subject matter submitted, the current state of the proceedings and the need for procedural economy.

Amended claims submitted at such a late stage as oral proceedings should be admitted only if clearly allowable in the sense that it can be quickly

ascertained that they overcome outstanding issues without raising new ones (T 1993/07 of 13 October 2013; T 2044/09 of 11 February 2014).

4.2 Auxiliary requests 1 and 3 were filed at the oral proceedings before the board and hence their admission is at the board's discretion.

4.3 The board acknowledges that these requests constitute attempts to overcome objections under Article 123(2) EPC discussed at the oral proceedings before the board.

4.4 In claim 1 of auxiliary request 1, the reference to "at least one" discrete capillary flow path has been deleted. The claim now refers to a single non-bibulous structure which has a plurality of discrete capillary flow paths, whereas the application as filed only discloses a plurality of non-bibulous structures having a plurality of discrete capillary flow paths. This raises the question, as submitted by the respondents, as to whether the combination of a single non-bibulous structure with a plurality of discrete capillary flow paths is directly and unambiguously derivable from the application as filed (Article 123(2) EPC). In view of this new issue, the board decides not to admit auxiliary request 1 into the proceedings.

4.5 Claim 1 of auxiliary request 3 defines the solid phase matrix as a non-bibulous structure, and further states that non-bibulous structures are impermeable structures having discrete capillary flow paths. In view of the discrepancy between the presence of a solid phase matrix in the claimed test article, which is a singular non-bibulous structure, and a general definition in the claim concerning non-bibulous structures in the plural form, the question of whether or not the claim is clear

arises (Article 84 EPC). Moreover, in view of the fact that it is not entirely clear from the wording of the claim whether or not the general statement relating to non-bibulous structures being impermeable structures having discrete capillary flow paths is a feature of the solid phase matrix referred to, the board has doubts as to the allowability of the amendment under Article 123(3) EPC. Consequently, the board considers that auxiliary request 3 raises new issues and decides not to admit it into the proceedings.

5. In view of the above, none of the admissible claim requests meets the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald

Decision electronically authenticated