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D E C I S I O N
of 10 September 2003

Case Number: T 1000/00 - 3.3.8

Application Number: 95101097.4

Publication Number: 0654659

IPC: G01N 33/52

Language of the proceedings: EN

Title of invention:
Defined volume test device

Patentee:
Roche Diagnostics Corporation

Opponent:
Lifescan Inc

Headword:
Test device/ROCHE

Relevant legal provisions:
EPC Art. 100(c)

Keyword:
"Main and auxiliary requests: added matter not contained in the earlier application as filed (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1000/00 - 3.3.8

D E C I S I O N
of the Technical Board of Appeal 3.2.8
of 10 September 2003

Appellant: (Proprietor of the patent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 7 July 2000 revoking European patent No. 0654659 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: L. Galligani
Members: T. J. H. Mennessier
C. Rennie-Smith

Summary of Facts and Submissions

I. The patentee (appellant) lodged an appeal against the decision of the opposition division dated 7 July 2000, whereby the European patent No. 0 654 659 was revoked.

II. The patent was based on application No. 95 101 097.4 which was a divisional application of the application No. 89 110 393.9 published with the publication number 0 345 781.

III. The patent had been opposed by one party on the grounds as set forth in Articles 100(a), (b) and (c) EPC that the invention did not involve an inventive step, was not sufficiently disclosed and contained added matter. Basis of the revocation were the granted claims which were considered by the opposition division to contain subject-matter extending beyond the content of the earlier application as filed.

IV. Granted claims consisted of 4 claims of which claim 1 read:

"A method for determining the amount of an analyte in a liquid sample compnsing [sic] applying the sample to the upper surface of reagent matrix layer which provides a determinate volume for sample and test reagents and is asymmetrically porous, having pores of progressively decreasing diameter from the upper surface to the lower surface of the reagent matrix layer and determining the amount of analyte from the lower surface of the reagent matrix layer."

V. The opponent(respondent) filed observations in reply to the statement of grounds of appeal. The appellant made additional written remarks in respect of which the respondent filed further observations.

VI. A communication under Article 11(2) of the Rules of Procedure of the Boards of Appeal presenting some preliminary and non-binding views of the board was sent to the parties together with the summons to oral proceedings.

VII. In reply to the board's communication, the appellant filed additional observations, with a letter dated 8 August 2003 and received per fax on 11 August 2003, together with an auxiliary request, the granted claims being the main request.

VIII. The auxiliary request consisted of 4 claims of which claim 1 read:

"A method for determining the amount of an analyte in a liquid sample comp**ri**sing applying the sample to the upper surface of reagent matrix layer which provides a determinate volume for sample and test reagents and is asymmetrically porous, having pores or [sic] progressively decreasing diameter from the upper surface to the lower surface of the reagent matrix layer**, wherein the reagent matrix layer has a blown-pore or open-pore structure,** and determining the amount of analyte from the lower surface of the reagent matrix layer." (bold-type characters added by the board in order to emphasize the difference from claim 1 of the main request [granted claim 1]).

IX. Oral proceedings took place on 10 September 2003. They were attended by both parties.

X. Regarding the earlier application No. 89 110 393.9, as the A2 publication (EP 0 345 781) and the documents as filed have exactly the same content, reference thereto will be made in the present decision using the A2 publication.

XI. The appellant's arguments in writing and during oral proceedings, insofar as they are relevant to the present decision, may be summarized as follows:

The earlier application as filed already disclosed a method which, as defined in claim 1 of either the main or the auxiliary request, employed a test device which only consisted of a reagent matrix layer comprising an asymmetrically porous member.

The passage in the earlier application on page 5, lines 47 to 52 stated that the asymmetrical porous member, in particular the one having a blown-pore or open-pore structure, "[could] serve as the reagent matrix layer without the use of additional membranes or layers". This clearly demonstrated that the earlier application contained the subject-matter of claim 1 as defined in either the main or the auxiliary request where the reagent matrix layer was used without additional absorbent and barrier layers.

An important feature of the asymmetrically porous membrane, which was described on page 5, line 56 to page 6, line 3 of the earlier application, was that the surface to volume ratio was very large, providing rapid

absorption of the sample and rapid, uniform wetting of the reagent matrix layer. This wetting allowed a determination which was not substantially effected by the presence of excess sample on the dosing surface of the reagent matrix layer.

Thus, the skilled person would have understood that the quantitative determination of the analyte without interference caused by excess sample on the dosing surface of the reagent matrix layer and without interference caused by cellular blood components were solved by the reagent matrix layer without the presence of an absorbent and a barrier layers.

The passage on page 6, lines 4 to 6 of the earlier application which stated that it was an advantage of this invention that the volume of the reagent matrix layer upon sample saturation might be precisely calculated "as any excess sample [was] assayed so rapidly that no interference with the quantitation reaction [was] observed" was an explicit reference to the use of an asymmetrically porous reagent porous matrix in a method for determining an analyte in the absence of an absorbent and a barrier layers.

XII. The respondent's arguments in writing and during oral proceedings, insofar as they are relevant to the present decision, may be summarized as follows:

The earlier application as filed consistently taught that a three-layer device is required. It was clearly indicated to the person skilled in the art that the method described could not be carried out without the presence of both the absorbent layer and the barrier

layer. There was absolutely no way in which the said person could derive directly and unambiguously from the earlier application that the reagent matrix layer should be used in the absence of the absorbent and barrier layers.

The earlier application as filed did not disclose a second and independent aspect relating to the method of claim 1 of either the main or the auxiliary request.

A reagent matrix layer comprising an asymmetrically porous membrane having progressively smaller pores from the upper surface of the reagent matrix layer to the lower surface of the reagent matrix layer was simply a preferred reagent matrix layer for use within a three-layer device. Such a reagent matrix layer was not independent from the requirement of a device having three layers. The earlier application as a whole clearly taught that the absorbent layer and the barrier layer were essential features of the device of the invention. Furthermore all references to a method of measuring the amount of analyte in a sample used a device having three layers. The examples confirmed to the skilled person that the method of carrying out the assay required the use of an absorbent layer and a barrier layer. There was nothing in the examples which in any way suggested that the reagent matrix layer could be used by itself.

The "additional membranes or layers" referred to in the earlier application on page 5, lines 51 and 52 was a reference to additional membranes or layers within the reagent matrix layer. The additional membranes or

layers were not the barrier layer and the absorbent layer.

The passage in the earlier application on page 5, line 52 to page 6, line 3 provided within it preferred and optional features for the reagent matrix layer. However, it had no bearing on the absorbent and barrier layers. It assumed that the absorbent and barrier layers were present.

There was no support in the passage of the earlier application on page 6, lines 4 to 6 for an independent embodiment relating to the use of an asymmetrical porous reagent matrix layer in a method for determining an analyte, an embodiment which was a device having the reagent matrix layer only.

XIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted or, alternatively, on the basis of the auxiliary request filed on 11 August 2003.

XIV. The respondent requested that the appeal be dismissed.

Reasons for the Decision

Main request (claim 1): Article 100(c) EPC

1. The question to be answered is whether claim 1 contains subject-matter which was not contained in the earlier application as filed.

2. Claim 1 is directed to a method for determining the amount of an analyte in a liquid sample based on the use of an **asymmetrically porous reagent matrix layer**, the concomitant use of both an absorbent and a barrier layers being not referred to therein.

3. The appellant contends that the claimed method is, at least implicitly, disclosed in the earlier application as filed. It is its view that from the overall content of the earlier application the person skilled in the art, while paying particular attention to specific passages on pages 5 and 6 of the description, would have derived that an asymmetrically porous reagent matrix layer, more particularly one having a blown-pore or open-pore structure, was appropriate, due to its inherent functions, for the determination of an analyte in a liquid sample without the need of concomitantly using both an absorbent and a barrier layers.

4. The board notes that the earlier application as filed is explicitly dealing with three-layer devices appropriate for determining the amount of an analyte in a liquid sample which comprise, in addition to a reagent matrix layer, both an absorbent and a barrier layers. Indeed, all the claims are directed either to such a three-layer device or a method using the same, the figures are views of a preferred three-layer device and in the experimental part of the description, in addition to the description of the preparation of a preferred asymmetrically porous reagent matrix layer, only specific uses of that layer as part of such a three-layer device for the performance of a series of assays are illustrated.

5. As for the rest of the description of the earlier application as filed, the board notes that asymmetrically porous reagent matrix layers as such are only discussed in two paragraphs on pages 5 and 6. Reference thereto is also made on page 3, at lines 23 to 27 but only in a statement which merely indicates that, according to a preferred embodiment, a three-layer device comprises an asymmetrically porous reagent matrix layer.

6. The first paragraph discussing asymmetrically porous reagent matrix layers is at lines 47 to 52 on page 5 of the earlier application as filed. It consists of three sentences:

6.1 In the first sentence (see lines 47 to 49), it is stated that, "Preferably, the reagent matrix layer **comprises** a porous member which is asymmetrically porous, having pores of progressively decreasing diameter in a progression from the upper (dosing) surface to the lower (determination) surface of the reagent matrix surface". The use of the term "comprises" is an indication that, apart from the asymmetrical porous member, the reagent matrix layer may contain one or more additional components.

6.2 In the second sentence (see lines 49 to 52), reference is made to blown-pore or open-pore structures which can serve as reagent matrix layers **"without the use of additional membranes or layers"** (emphasis added by the board).

6.2.1 This wording is interpreted in quite different ways by the parties. The appellant considers it to be an

indisputable indication that an asymmetrical porous reagent matrix layer may serve for the determination of an analyte without the use of both an absorbent and a barrier layers and, thereby, contributes to an implicit disclosure of the claimed method. The respondent considers that the same wording shows that an asymmetrical porous reagent matrix layer having a blown-pore or open-pore structure need not comprise within it any additional components such as one or more membranes or layers.

6.2.2 The board is convinced that the latter interpretation is the correct one because it is in line both with the wording "..*, the reagent matrix layer **comprises** a porous member which is asymetrically porous*" (emphasis added by the board) used at the beginning of the paragraph (see page 5, line 47), which allows the possibility that the reagent matrix layer may **comprise** other components in addition to the asymmetrically porous member; and with the statement found on lines 30 and 31 of the same page 5 of the earlier application which indicates that the reagent matrix layer can be a single membrane **or may be formed of a plurality of layers**. The layers meant here are strictly those constituting the matrix layer **not** the absorbent and the barrier layers which complete the device.

6.3 In the third sentence (see lines 52 to 55), the asymmetrically porous reagent matrix layers are acknowledged to be capable of separating cellular blood components. According to a further statement at lines 32 to 34 on the same page 5, which reads "The upper portion of the reagent matrix layer which includes the dosing surface of reagent matrix layer

contains pores which filters out or entrap particulate matter in the sample, particularly red blood cells", this appears not to be a feature specific for asymmetrical porous layers but a general feature of any reagent matrix layers, whether asymmetrically porous or not, referred to in the application.

7. The second paragraph discussing asymmetrical porous reagent matrix layers runs from line 56 on page 5 to line 3 on page 6. It stresses the point that the surface to volume ratio of the asymmetrical reagent matrix layers provides a rapid and uniform absorption of the sample.

7.1 The board notes that the provision of such an absorption of the sample is a general feature expected from any reagent matrix layer, whether asymmetrically porous or not, referred to in the earlier application (see, in this respect, the passage on page 4, lines 3 and 4 which reads "The reagent matrix layer is **quickly** absorbent, and sample which is present on its surface **quickly** saturates the reagent matrix layer" and the passage on page 7, line 23 which, for the preparation of the reagent matrix layers referred to in the application, points to a reagent such as cellulose acetate "which facilitates **uniform** wetting of the reagent matrix layer").

7.2 There can be no doubt that the consequence of the rapid and uniform absorption of the sample by the reagent matrix layer results in the dried reagents being dissolved and the analyte being placed in close proximity with the reagents, whether the reagent matrix layer is asymmetrically porous or not, as mentioned in

the second sentence of the paragraph (see the sentence bridging pages 5 and 6).

7.3 Therefore, the remark contained in the third sentence of the paragraph (see lines 1 to 3 on page 6) that the rapid, uniform wetting of the reagent matrix layer allows a determination which is not substantially affected by the presence of excess sample on the dosing surface of the reagent matrix layer, has to be considered to apply to any reagent matrix layers referred to in the application, whether they are asymmetrically porous or not.

8. From the two afore-mentioned paragraphs discussing the asymmetrically porous reagent matrix layers, the person skilled in the art would not have derived that such layers have features not shared by other reagent matrix layers which would have rendered them appropriate for the determination of the amount of an analyte in a liquid sample independently from the concomitant use of an absorbent and a barrier layers. Moreover, looking at the experimental part of the description, which refers to a "*BTS Asymmetric membrane*", one of the two preferred membranes referred to in the first of said paragraphs (see page 5, line 50), the skilled person would have had no doubts that this membrane was to be used as part of a three-layer device also comprising an absorbent layer and a barrier layer.

9. The appellant also relies on a sentence that follows those paragraphs at lines 4 to 6 on page 6 of the earlier application which reads: "*It is an advantage of this invention that the volume of the reagent matrix layer upon sample saturation may be precisely*

calculated, as any excess sample is either absorbed by the absorbent layer or assayed so rapidly that no reference with the quantitation reaction is observed.".

10. The board does not consider this sentence to refer implicitly to an asymmetrically porous reagent matrix layer used as a device for determining the amount of an analyte in a liquid sample in the absence of both an absorbent and a barrier layers. The sentence merely refers to the absorption properties of the reagent matrix layer without giving any hint of the possibility of using it independently from the absorbent and the barrier layers.

11. The board concludes that the appellant has failed to point to any passage or part of the earlier description which would have provided an implicit or explicit support for a method as defined in claim 1. Rather, the passages especially referred to on pages 5 and 6 by the appellant are considered to be part of a section of the description from line 24 on page 5 onwards describing the technical features and various embodiments of the reagent matrix layer as part of a three-layer device also comprising an absorbent layer and a barrier layer.

12. Therefore, claim 1 contains matter which was not already contained in the earlier application as filed.

Auxiliary request (claim 1): Article 100(c) EPC

13. Claim 1 of the auxiliary request differs from claim 1 of the main request only in that it has been specified therein that the asymetrically porous reagent matrix layer has a blown-pore or open-pore structure.

Therefore, claim 1 of the auxiliary request is also directed to a method for determining the amount of an analyte in a liquid sample based on the use of an asymmetrically porous reagent matrix layer only, ie to subject-matter which has been considered in the above paragraphs to contain matter which was not already contained in the earlier application as filed.

Conclusion

14. The ground for opposition mentioned in Article 100(c) EPC actually prejudices the maintenance of the patent on the basis of either the main or the auxiliary request.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Wolinski L. Galligani