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D E C I S I O N
of 10 November 2000

Case Number: T 0432/96 - 3.3.4

Application Number: 87308227.5

Publication Number: 0260965

IPC: G01N 33/543

Language of the proceedings: EN

Title of invention:
Immunodiagnostic device

Patentee:
PACIFIC BIOTECH INC.

Opponent:
Abbott Laboratories

Headword:
Immunodiagnostic device/PACIFIC BIOTECH

Relevant legal provisions:
EPC Art. 123(2)(3), 54, 56

Keyword:
"Main request: added matter (yes)"
"Auxiliary request: added matter (no)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
T 0020/81, T 0268/89

Catchword:
-



Case Number: T 0432/96 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 10 November 2000

Appellant: Abbott Laboratories
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 2 February 1996
rejecting the opposition filed against European
patent No. 0 260 965 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: L. Galligani
Members: R. E. Gramaglia
C. Holtz

Summary of Facts and Submissions

I. The appeal lies from the decision of the opposition division rejecting the opposition against European patent No. 0 260 965 (application No. 87 308 227.5) which was granted on the basis of 12 claims. Claim 1 as granted read as follows:

"1. An immunoassay device having a housing (10) with at least one opening (26) therethrough for introduction of a liquid sample into the housing (10), a matrix (24) of porous material in the housing (10) adapted to be contacted by the liquid sample, absorbent material (20, 22) in contact with the matrix (24), and at least one immunological reagent on the matrix (24), characterized in that the device further comprises a desiccant material in the housing."

Dependent claims 2 to 10 related to specific embodiments of the device of claim 1, while claims 11 and 12 covered methods for performing immunoassays utilizing the device of claims 1 to 10.

II. The following documents are referred to in the present decision:

(D2) EP-A-0 186 100;

(R1) US-A-3,888,629;

(R2) EP-B1-0 097 952;

(R5) US-A-3,820,309;

(R6) US-A-3,722,188;

- (R7) Declaration by Eugene Fan to the USPTO dated 6 November 1992;
- (R9) The Merck Index, 11th Edition (Merck and Company, Inc., Rahway, N.J. USA), page 1357 (1989);
- (R11) US-A-4,330,627;
- (R13) US-A-3,607,093;
- (R14) WO-A-86/04421;
- (R15) US-A-4,218,421.

Of these, documents (R13) to (R15) were filed by the appellant (opponent) during the course of the appeal proceedings.

- III. The board issued a communication pursuant to Article 11(2) of the rules of procedure of the boards of appeal expressing its provisional opinion.
- IV. On 15 May 2000, the respondent (patentee) filed a new main request (claims 1 to 12), of which claim 1 read as follows (the amendments vis-à-vis granted claim 1 are shown in bold):

"1. An immunoassay device having a housing (10) with at least one opening (26) therethrough for introduction of a liquid sample into the housing (10), a matrix (24) of porous material in the housing (10) adapted to be contacted by the liquid sample, absorbent material (20, 22) in contact with the matrix (24), and at least one immunological reagent on the matrix (24), characterized

in that the device further comprises a desiccant material in the housing, **with the proviso that the desiccant material is located away from the immunological reagent.**"

The remaining claims were as granted.

- V. Oral proceedings were held on 10 November 2000, during which the respondent filed an auxiliary request (claims 1 to 11), of which claim 1 read as follows (the amendments vis-à-vis granted claim 1 are shown by way of deletions and in bold):

"1. An immunoassay device having a housing (10) with at least one opening (26) therethrough for introduction of a liquid sample into the housing (10), a matrix (24) of porous material in the housing (10) adapted to be contacted by the liquid sample, absorbent material (20, 22) in contact with the matrix (24), and at least one immunological reagent on the matrix (24), characterized in that the device further comprises a desiccant **moisture-absorbent** material in the housing, **and wherein the housing comprises two compartments, one compartment containing the matrix, and a second compartment containing the moisture-absorbent material, the first compartment being in communication with the second compartment.**"

Dependent claims 2 to 9 were as granted; claims 10 and 11 corresponded to claims 11 and 12 as granted.

- VI. The submissions provided by the appellant can be summarized as follows:

(i) With respect to the main request:

Article 123(2) EPC

- In the application as filed there was a basis for a device comprising two chambers, one of which containing the matrix, the other containing the desiccant. However, present claim 1 also covered a device comprising one single chamber containing both the matrix and the desiccant anywhere inside it, but located away from the immunological reagent. This embodiment found no basis in the application as filed and thus represented added subject-matter.
- The replacement of the original term "moisture absorbent chemical" with "desiccant material" represented added subject-matter.

(ii) With respect to the auxiliary request:

Article 123(2) EPC

- The application as filed, under the heading "Summary of the invention" (cf. page 5 of the published (A2) document; hereinafter "A2-application") listed a series of features stated to be fundamental for achieving the alleged good results. However, the omission of these essential features in claim 1 represented added subject-matter.
- The replacement of the term "chambers" ("A2-application", page 4, line 29) with "compartments" (claim 1) represented added subject-matter.

Article 123(3) EPC

- Claim 1 was broader in scope than granted claim 1 because the term "desiccant material" had been replaced with the broader wording "moisture-absorbent material".

Novelty (Article 54 EPC)

- Document (R2) disclosed a multilayer analytical element located in a housing (see eg Figure 6). The layers were a spreading sheet containing a labelled analyte, a sharing sheet and a reaction sheet containing an immunological reagent. It was stated on page 8, lines 4 to 6 of that document that the spreading sheet could contain a preserving agent having hygroscopic properties. Since the layers document (R2) could be considered as compartments, claim 1 lacked novelty.

Inventive step (Article 56 EPC)

- Document (R1) disclosed an immunoassay device according to claim 1 at issue, with the only difference that the desiccant was located outside the reaction cell's housing, in an external envelope also containing the reaction cell. Departing from document (R1) as the closest prior art and considering the problem to be solved by the patent in suit as being improving the sensitivity, the ease and speed of performance and the long term room temperature stability of the immunodiagnostic device of document (R1), there was no evidence that the patent in suit actually solved the above problem. But even assuming that

the skilled person was trying to improve the device of document (R1), he/she would have arrived at the claimed solution in the light of prior art documents disclosing solid carriers impregnated with antigens stored in a dark bottle in the presence of a desiccant (document (R13)), in an air tight, moisture-free environment (document (R14)) or within the chamber (document (R15)).

- The claimed solution could have easily been arrived at by combining the teaching of document (R1) with that of document (R11). This document disclosed a tray for carrying out tests comprising a plurality of test chambers (channels) accommodating a reagent paper or disc. The device also comprised a separate chamber wherein a desiccant was located, communicating with all the test channels.
- If it were assumed that the problem to be solved by the patent in suit was the provision of alternative means to those of document (R1) for protecting the immunological reagents from moisture, the skilled person would have been induced to adopt the sole existing alternative solution of introducing the desiccant into the device's housing.
- Departing from document (R2) as the closest prior art, this document suggested the incorporation of a desiccant inside the housing (see page 8, line 5). The skilled person would have arrived at the only possible solution as claimed in claim 1 either by departing from this document alone or by combining the teaching thereof with that of

documents (R5), (R6) or (R10).

- Document (R15) disclosed a device for storing and dispensing test strips having a desiccant within the device. Departing from this document as the closest prior art, the problem to be solved would have been to adapt the device of document (R15) to immunochemical reactions. This could have been done in an obvious manner by providing an immunological reagent on the test strips.
- Departing from the device disclosed by document (D2) as closest prior art, the skilled person would have been induced to introduce a desiccant into this device.

VII. The submissions provided by the respondent can be summarized as follows:

(i) With respect to the main request:

Article 123(2) EPC

- There was a basis on page 4, lines 51 to 52 of the "A2-application" ("a single chamber will perform adequately provided the chemicals are otherwise associated with it") in combination with the drawings as filed (showing that the desiccant material was located away from the immunological reagent) for a device comprising one single chamber containing both the matrix and the desiccant, wherein the desiccant had to be located away from the immunological reagent, as recited in the disclaimer in claim 1.

(ii) With respect to the auxiliary request:

Article 123(2) EPC

- There was a basis on page 4, lines 24 to 28 and in Figure 2 of the "A2-application" for a device comprising two compartments, one compartment containing the matrix, and a second compartment containing the moisture-absorbent material, the first compartment being in communication with the second compartment.

Novelty (Article 54 EPC)

- In the claimed device, the matrix comprising the immunological reagent was physically separated from the desiccant material, while in the multilayer element of document (R2), the desiccant material was in close contact with the immunological reagent. Moreover, if one of the three layers disclosed by document (R2) actually comprised a desiccant, the device would not be able to work because the liquid sample would be absorbed by the desiccant.

Inventive step (Article 56 EPC)

- The problem to be solved by the patent in suit was stated on page 4, lines 24 to 25 and page 7, lines 11 to 19 as being to improve the sensitivity and the long term room temperature stability of immunodiagnostic devices. This problem had been solved by "the utilization of a suitable chemical drying agent situated in chamber 18" (page 7, lines 12 to 13). The experimental results of

Table 2 showed that this goal had been achieved.

- It was stated in document (R1) that moisture "is not found to be a problem". Therefore, anyone reading document (R1) would have had neither an incentive to consider placing the desiccant anywhere other than in the envelope outside the housing of the reaction cell, nor to look for other documents such as documents (R2), (R13) or (R14) in the hope of finding the solution to a problem which document (R1) said that it did not exist.

- The purpose of the desiccant in the device of document (R11) was to dry the channels rather than the reagent disks. Therefore the skilled person would not have combined document (R1) with document (R11), relating to a completely different apparatus, in which a desiccant was introduced for a different purpose.

VIII. The appellant (opponent) requested that the decision under appeal be set aside and that the European patent No. 0 260 965 be revoked.

The respondent (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of either the main request as submitted on 15 May 2000 or the auxiliary request submitted in the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

Main request

Article 123(2) EPC

2. The appellant argues that replacement of the term "moisture absorbent chemical" used in the application as filed with "desiccant" represents added subject-matter, all the more so as this feature has not been told to be essential. Yet the board disagrees since in the "A2-application" on page 3, line 63, use is made of the term "desiccant" as a synonym for "moisture absorbent chemical" and moreover it is stated on page 3, line 59 that the location of the desiccant is "an additional feature of the subject invention that contributes to its sensitivity".

3. The respondent argues that there is a basis on page 4, lines 51 to 52 of the "A2-application" in combination with the drawings as filed for a single-chambered device wherein the desiccant material is located away from the immunological reagent. However, in the board's judgement, while it is true that the drawings as filed show that the desiccant material is located away from the immunological reagent, they relate to a two-chambered device, not a single-chambered one. Therefore, it is not permissible to combine this technical information with the statement on page 4, lines 51 to 52 that "a single chamber will perform adequately provided the chemicals are otherwise associated with it". This passage has thus to be interpreted by its own. But no direct and unambiguous information can be derived therefrom that the desiccant material has to be located within the sole chamber but away from the immunological reagent. Consequently, the subject-matter of claim 1 infringes Article 123(2) EPC

and the main request comprising this claim has to be refused.

Auxiliary request

Article 123(2)(3) EPC

3. At the oral proceedings, the appellant objected that the claims extended beyond the content of the application as filed because claim 1 did not comprise certain technical features which in the application as filed were stated to be essential for the achievement of alleged good results (see paragraph VI(ii) supra). The board, however, refused to allow this issue into the proceedings, as the appellant had withdrawn the opposition under Article 100(c) EPC (see the minutes of the oral proceedings before the opposition division, page 4, section 2.2.A). This objection of "missing essential technical features" has also not been raised in connection with the amendments made by the respondent. In view of this, it would have been unfair against the other party if the board had re-admitted this already settled issue into the proceedings, bearing in mind that the appellant's only argument under Article 123(2) EPC on appeal was that no basis could be found in the application as filed for a device comprising one single chamber containing both the matrix and the desiccant anywhere inside it, as covered by granted claim 1.

4. As for the appellant's argument that the replacement of the term "chambers" ("A2-application", page 4, line 29) with "compartments" (claim 1) represents added subject-matter, the board notes that these two terms are used interchangeably in the "A2-application" for designating a cavity delimited by walls (compare page 4, line 29:

"two chambers" with page 3, lines 60 of the "A2-application": "two compartments").

5. Finally, contrary to the appellant's opinion, the board is unable to view the wording "moisture-absorbent material" as being broader than the term "desiccant material", of which it is a mere synonym (see 2 supra). Therefore, claim 1 of the auxiliary request satisfies the requirements of Article 123(2)(3) EPC.

Novelty

6. The appellant maintains that claim 1 at issue lacks novelty over document (R2), once the layers of document (R2) are considered as compartments. In the board's view, even assuming that a layer is a compartment (which is questionable because the former is not delimited by walls), it has to be noted that the wording in claim 1 "wherein the housing comprises two compartments, one compartment containing the matrix, and a second compartment containing the moisture-absorbent material" is a distinguishing technical feature implying that in the claimed device, the matrix comprising the immunological reagent is physically separated from the desiccant material, as demonstrated by the two compartments comprising each of them. In the multilayer element of document (R2), however, the desiccant material is admixed with the immunological reagent, in this case a labelled antigen (see e.g., Figure 1 in combination with page 10, lines 14 to 17, page 7, lines 44 to 45 and page 8, line 3). Moreover, doubts arise as to whether the skilled person would seriously contemplate incorporating a desiccant into any of the three layers disclosed by document (R2), since the liquid sample would be absorbed by the

desiccant. This view is supported by the fact that document (R2) does not exemplify such questionable embodiments but merely mentions on page 8, line 5, the incorporation in the spreading sheet of sodium azide, which is a "bacteriostatic agent" (see patent in suit, page 8, line 25) and not a desiccant (it decomposes upon heating: see document (R9)). In conclusion, the subject-matter of claim 1 is considered to be novel. This conclusion also applies to claims 2 to 11, whose novelty depends on that of claim 1.

Inventive step

Closest prior art

7. It is established jurisprudence of the boards of appeal that the assessment of inventive step has to be preceded by the determination of the technical problem which the invention addresses and solves, and that the technical problem is to be formulated in the light of the closest state of the art. In order to apply this approach, it is essential to start with establishing the closest prior art. In the present case, this requires that the claimed invention should be compared with the art concerned with a similar device which requires the **minimum** of structural and functional modifications.

8. In the board's view, a device satisfying this requirement is disclosed in column 1, lines 26 to 30 of document (R1), which describes "a reaction cell, suitable for use in immunoassays, comprising a container having therein a matrix pad and a support for the matrix pad allowing the passage of liquid through the pad" in combination with column 5, lines 27 to 30 thereof: "Optionally, the reaction cell containing a

freeze-dried antigen (or antibody) may be sealed in a plastic envelope, which may contain a desiccant, to prevent absorption of moisture". The immunoassay device according to claim 1 at issue differs therefrom in that the desiccant is located in a second chamber within the reaction cell's housing rather than outside it.

9. The appellant also argues that the skilled person could have departed from documents (D2), (R2) or (R15) as closest prior art for arriving at the claimed device (see paragraph VI supra).

As for document (D2), though, no reference to the presence of a desiccant is made at all. As regards the "disposable container" of document (R15), Figure 2 thereof shows how far away it is from the claimed immunoassay device. Turning to document (R2), the latter relates to a multilayer element wherein a desiccant material, **if any**, is not physically separated from the immunological reagent (see point 6 supra), unlike document (R1) and claim 1 at issue. Therefore, the conclusion cannot be drawn that documents (D2), (R2) or (R15) disclose something which requires the minimum of structural and functional modifications for it to be transformed into the device of claim 1 at issue. In view of this, the board does not consider that these documents can represent the closest prior art in the light of which the technical problem underlying the disputed patent should be formulated.

Problem to be solved

10. The respondent maintains that using a suitable chemical drying agent situated in a separate chamber inside the device solves the problem of improving the sensitivity

and the long term room temperature stability of immunodiagnostic devices. There is indeed a passage on page 3, line 59 of the "A2-application", according to which the location of the desiccant is "an additional feature of the subject invention that contributes to its sensitivity". However, the board observes that this statement is contradicted by the passage on page 4, line 52 (ibidem), according to which the claimed device performs adequately even if the desiccant is located outside the housing. Furthermore, there is no evidence before the board that the experimental tests reported in Tables 1 and 2 of the patent actually compare the sensitivity of the claimed diagnostic device having the desiccant located in a separate chamber inside the housing vis-à-vis diagnostic devices having the desiccant located outside the housing. In accordance with decision T 20/81 (OJ EPO 1982, 217), however, advantages not supported by sufficient evidence cannot be taken into consideration in determining the underlying technical problem and hence in assessing the inventive step.

11. During the proceedings before the opposition division, the respondent provided a declaration by Eugene Fan to the USPTO (document (R7)) which pointed out a series of advantages exhibited by the claimed device vis-à-vis a similar device having the desiccant located outside the housing. Point 7 of document (R7) relates to packaging advantages, while point 8 emphasizes the ease of manufacture of the claimed immunoassay device (286 pieces/hr) compared with that of the prior art one (192 pieces/hr). However, all these technical advantages pointed out in document (R7) cannot be derived from a comparison of the application as filed with the prior art. Therefore, they cannot contribute to the

formulation of the problem solved by the claimed subject-matter (see e.g. decision T 268/89, OJ EPO 1994, 50).

12. Consequently, the objective technical problem solved by the claimed subject-matter vis-à-vis the closest prior art represented by the diagnostic device disclosed by document (R1) has to be restated to meet a less ambitious objective, namely the provision of an alternative device.

13. Contrary to the appellant's opinion, the fact that the claimed device does not exhibit any advantageous properties vis-à-vis the immunoassay device of document (R1) does not by itself imply that it lacks an inventive step. This is because, while an advantageous effect might be an indication of inventive step, the decisive question is always whether it would have been obvious for the skilled person to arrive at something falling under the terms of a claim at all. In the present situation, the proposed solution might prima facie seem obvious in its simple outline. However, as repeatedly emphasized in the case law of the boards of appeal, in the assessment of inventive step it is important to avoid any ex-post-facto analysis, especially in cases where the proposed solution is simple.

14. Bearing this in mind, it should be noted that document (R1) representing the closest prior art states in column 5, lines 30 to 31 that moisture "is not found to be a problem". Therefore, this document taken alone does not encourage the skilled person to consider placing the desiccant anywhere other than in the "plastic envelope", outside the housing of the reaction

cell (columns 5, lines 28 to 29), since no moisture problem, let alone any "desiccant positioning" problem, has been noted there.

15. The appellant argues that the skilled person would have arrived at the claimed device by combining the teaching of document (R1) with that of prior art documents disclosing solid carriers impregnated with immunological reagents stored in air tight housings (e.g. a bottle) in the presence of a desiccant (see documents (R13), (R14)) and (R15)).

In the board's judgement, the skilled person seeking an alternative to the device of document (R1) would not have necessarily focused his/her attention to the desiccant issue in order to find an alternative solution to a problem of "desiccant positioning", the existence of which document (R1) denies. But assuming for the sake of argument that on focusing onto such an issue, he/she would have taken documents (R13), (R14) and (R15) into consideration, these documents merely confirm the fundamental principle according to which a desiccant material has to be present in an air tight enclosure (e.g. the dark bottle of document (R13)). This principle is also taught by document (R1), since it refers to a sealed plastic envelope which contains the desiccant. The air tight containers of documents (R13), (R14) and (R15) additionally comprise a "nude" (i.e. not enclosed in a housing as that of document (R1)) solid matrix impregnated with the immunological reagents. In the board's view, combining the teaching of document (R1) with that of documents (R13), (R14) and (R15) would not necessarily prompt the skilled person to include a desiccant material in the housing of document (R1). Other technically meaningful

combinations of features could have been an air-tight rectangularly shaped box comprising both the reaction cell and a desiccant bag glued inside it, the replacement of the sealed plastic envelope according to document (R1) with e.g, the dark bottle of document (R13) or with the air-tight, moisture-free container of document (R14)(see page 21, line 2). Thus, by avoiding ex-post-facto analysis, the conclusion cannot be drawn that combining the teaching of document (R1) with that of documents (R13), (R14) and (R15) inevitably leads to a single-chambered device according to document (R1) comprising a desiccant material inside the housing, **let alone** to a two-chambered device according to claim 1 at issue.

16. The appellant maintains that the claimed solution could have easily been arrived at by combining the teaching of document (R1) with that of document (R11).

This document discloses a tray for carrying out tests comprising a plurality of test chambers (channels) accommodating a reagent paper or disc. The device also comprises a separate chamber wherein a desiccant is located, which chamber communicates with all the test channels. In the board's opinion, the purpose of the desiccant in the device of document (R11) is to dry the channels (cf. column 1, lines 55 to 57: "problems have been encountered in that unwanted moisture may develop in the testing channels") rather than the reagent disks. Therefore, the skilled person would not combine document (R1) with document (R11), relating to a completely different and complex apparatus, in which a desiccant is introduced for a purpose other than that of keeping the immunological reagents moisture-free.

17. In conclusion, the subject-matter of claim 1 is considered to involve an inventive step. This conclusion also applies to claims 2 to 11, the inventive step of which depends on that of claim 1. Therefore, none of the objections raised prevents the claims of the auxiliary request from being patentable under the EPC.

Adaptation of the description

18. No objections have been raised by the appellant to the amendments to the description effected to bring it into line with the claims of the auxiliary request and the board also sees none.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the auxiliary request submitted in the oral proceedings, amended pages 2 to 10 of the description also submitted in the oral proceedings, page 11 of the description as granted and Figures 1 to 3 as granted.

The Registrar:

The Chairman:

U. Bultmann

L. Galligani