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**Datasheet for the decision
of 4 May 2012**

Case Number: T 1038/08 - 3.4.02

Application Number: 04781418.1

Publication Number: 1678507

IPC: G01N35/00

Language of the proceedings: EN

Title of invention:

COMPACT, INTEGRATED SYSTEM FOR PROCESSING TEST SAMPLES

Applicant:

bioMerieux, Inc.

Headword:

Relevant legal provisions:

EPC Art. 84, 56

Keyword:

Clarity - Claims 1, 13 (yes)

Inventive Step - Claims 1, 13 (yes)

Decisions cited:

Catchword:



Case Number: T1038/08 - 3.4.02

D E C I S I O N
of the Technical Board of Appeal 3.4.02
of 4 May 2012

Appellant: bioMerieux, Inc.
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Representative: Froud, Clive
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted 7 February 2008
refusing European patent application No.
04781418.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: A. Klein
Members: M. Rayner
L. Bühler

Summary of Facts and Submissions

I. The applicant appealed against the decision of the examining division refusing European Patent Application number 04781418.1. The patent application concerns an integrated system and method for processing a plurality of test samples. In the following reference is made to documents using the notation below:-

D1 US-A-6 086 824
D2 US-A-4 118 280.

II. In the decision under appeal, the examining division considered the subject matter of the independent claims according to the main request before it to lack both clarity and an inventive step. The division's reasoning included the following.

Clarity

a) In claim 1 {system claim}, the function of the slots of the carrier is not clear because there is no defined link between the optical sensors and the slots.

b) In claim 2 {dependent claim} the transport system is defined to move the carrier between the loading station and the modules, yet it appears from the description that the transport system delivers cards and not carriers from the rotating carrousel to the reader station. There is therefore an inconsistency between the claim and the description.

c) Claim 15 {system claim} does not entirely correspond to claim 1 giving rise to lack of clarity, for example there is no definition concerning the carriers having slots so that the definition of the optical system of the transport device is incomplete.

Inventive Step

A difference between the subject-matter of both the system claim 1 and the method claim with respect to disclosure of document D1 is that the carrier is manually loaded into the carrier and test device processing subsystem after completion of vacuum loading of said test samples. A problem to be solved is to realise a more compact, less costly and less complex sample processing instrument, and therefore more suited for small and medium scale sample testing enterprises. The solution proposed in the independent claims cannot be considered as involving an inventive step because manual operation of the placement of the carrier into a vacuum chamber before the placement into a reader subsystem or system is well known in the prior art. In document D1 it is mentioned with reference to document D2 that the operator manually inserts the carrier in the vacuum chamber of the filler sealer and afterwards manually places the carrier in the reader. Integrating these two parts in a single system does not involve an inventive step, especially as there is no mechanical interaction between them. Document D1 points out the difficulties that arises in providing an automatic transport system for moving the sample cards and receptacles about the machine to the various stations so that it is clear the skilled person would have noticed that the fully automatic system of document D1 could be simplified by making some parts of it manual. This process does not result in any unexpected effect. In decision T0505/96, the Board of Appeal indicated that the simplification of existing complicated technology in situations in which the advantages of the simplification could be expected (no unexpected effect)

must be considered as to be part of the normal work of the person skilled in the art.

III. The appellant requested that the decision under appeal be set aside and a patent granted. Oral proceedings were requested on an auxiliary basis.

IV. In support of its case the appellant argued as follows.

Clarity

The independent claims have been clarified. Amendments and their support include the following.

"A carrier transport system (1000) having optical interrupt sensors for moving a carrier" in claim 1 may be found in original pages 16, 21, 39, 41 and 42, for example.

"... wherein the said one or more optical sensors detect interrupt slots (212) formed in the said carrier allowing the said carrier's location to be monitored continuously ..." in claim 1 (and claim 14) may be found in the original specification at page 42, lines 5-12.

Moreover, the method claim recites that the receptacle and the test sample devices are "carried by a carrier". It is submitted that what is now claimed is clear, sufficient and supported.

Inventive Step

Faced with the challenge presented to the present inventors to offer a more compact, simpler and low cost instrument, there is nothing in document D1 which

suggests the particular arrangement of the instrument now recited in the independent claims. The examining division would appear to have misunderstood the disclosure of document D1 in relation to document D2. The functions of vacuum loading and sealing of the cards are part of the functionality of the separate filler sealer module. The present invention is not merely a combination of a filler sealer module and a reading module; rather the instrument is arranged such that it includes the separate vacuum station adapted for manual insertion of a carrier holding test sample cards and test samples, and a separate carrier and test device processing subsystem which includes the sealing station as one of the modules.

V. Consequent to the auxiliary request of the appellant, the board appointed oral proceedings. During the oral proceedings, as well as filing an amended set of claims, the representative of the appellant explained that he would not expect to separate filling from sealing as is done according to the invention because, after filling, this allows exposure of the cards to atmosphere until sealing takes place in the carrier and test device processing subsystem.

VI. Independent claims 1 and 13 are worded as follows.

"1. An integrated system (10) for processing a plurality of test samples (106) and test sample devices (100) for receiving the said test samples, the said test samples received in individual fluid receptacles, characterized in that it comprises:
a carrier transport system (1000) having optical interrupt sensors for moving a carrier;
a carrier (200) having slots (206, 202) formed therein for carrying a plurality of the said individual fluid

receptacles and a plurality of the said test sample devices, each of the said test sample devices placed in fluid communication with a test sample stored in one of the said individual fluid receptacles;

a vacuum station (300) adapted for manual insertion of the said carrier into the said vacuum station and manual removal of the said carrier from the said vacuum station, the said vacuum station further comprising a source of vacuum (306), the said vacuum source controlled so as to load the said test samples from the said individual fluid receptacles into respective test sample devices;

and

a carrier and test device processing subsystem (50) remote from the said vacuum station, comprising (1) the said carrier transport system (1000) moving the said carrier within the carrier and test device processing subsystem, the carrier transport system including one or more optical sensors (1050A, 1050B, 1050C) for sensing the position of the said carrier within the carrier and test device processing subsystem, and (2) modules for processing the said carrier and test sample devices, the said modules including a sealing station (400) sealing the said test sample devices, and a module (800) for conducting optical measurements of the said test sample devices, wherein the said carrier and test device processing subsystem and the said vacuum station are integrated into a single instrument and wherein the said carrier is manually loaded into said carrier and test device processing subsystem after completion of vacuum loading of the said test sample devices (100), wherein the said carrier transport system moves the said carrier along a single longitudinal axis between a carrier loading station and unloading station (16) in which the said carrier is

received and the said modules; and wherein the said one or more optical sensors detect interrupt slots (212) formed in the bottom of the said carrier allowing the said carrier's location to be monitored continuously.

13. A method for processing a plurality of test samples contained in open receptacles with test sample devices, the said receptacles and test sample devices carried by a carrier; each of the said test sample devices having a transfer tube providing fluid communication between the said test sample device and one of the said fluid receptacles received in the said carrier; characterized in that it comprises:

manually placing the said carrier into a vacuum station having a chamber and applying vacuum to the said vacuum station chamber thereby to transfer the said test samples into the said test sample devices as a batch; manually removing the said carrier from the said vacuum station chamber after the said transfer has been completed;

manually placing the said carrier into an automated carrier and test device processing subsystem remote from the said vacuum station;

automatically moving the said carrier with an optically-controlled transport system in the said carrier and test device processing subsystem, the said carrier transport including one or more optical sensors for sensing the position of the said carrier within the carrier and test device processing subsystem wherein the said carrier transport system moves the said carrier along a single longitudinal axis between a carrier loading and unloading station and to modules automatically (a) sealing the said test sample devices, (b) incubating the said test sample devices, and (c) reading the said test sample devices;

and

wherein the said vacuum station and the said carrier and test device processing subsystem are integrated into a single test sample processing instrument; and wherein the said one or more optical sensors detect the said slots formed in the said carrier allowing the said carrier's location to be monitored continuously."

VII. At the end of the oral proceedings, the board gave its decision.

Reasons for the Decision

1. The appeal is admissible.
2. Claim 1 - Clarity
 - 2.1 The objection of the examining division that there is no defined link between the optical sensors and the slots can be considered met in amended claim 1 because of the recitation that "said one or more optical sensors detect interrupt slots (212) formed in the bottom of the said carrier allowing the said carrier's location to be monitored continuously".
 - 2.2 Claim 1, as amended, recites that the carrier and test device processing system comprises the carrier transport system and modules for processing the carrier and test sample devices so no inconsistency between claim and description as seen by the examining division exists (see section II(b) of the Facts and Submissions above).
3. Claim 1 - Substantive Patentability
 - 3.1 There are a number of differences between the subject matter of claim 1 and the subject matter disclosed in

document D1. In addition to the differences established by the examining division, the claim as now amended refers, for example, to the feature that "said carrier transport system moves the said carrier along a single longitudinal axis between a carrier loading station and unloading station" and that "...one or more optical sensors detect interrupt slots (212)...".

In the board's view, the problem addressed by the novel features, as argued by the appellant or recognised by the examining division, can be considered that of providing a more compact, simpler and low cost instrument.

- 3.2 While the view of the examining division that "manual operation of the placement of the carrier into a vacuum chamber before the placement into a reader subsystem or system is well known in the prior art" is, in itself, correct, this view does not give a complete view of what is claimed. The reason for this is that document D2 discloses a stand alone vacuum and filling sealing machine. In other words, not only is the carrier placed in a vacuum chamber before placement into a reader subsystem, but it is also sealed before any such placement. The consequence of this situation is that in making a combination of the teachings of documents D1 and D2, the skilled person would have removed not only the vacuum chamber, but also the sealing station 400 from document D1 in order to correspond with document D2. It is therefore not just a matter of integrating the two known parts, as is, in a single system as contended by the examining division. Had that approach been taken, the structure claimed in claim 1 would not have been reached because claim 1 requires a sealing station not associated with the vacuum chamber as

taught by document D2, but in the carrier and test processing subsystem.

3.3 Not only would a combination documents D1 and D2 not lead to the claimed subject matter, but the board is also not aware of any convincing counter argument to the appellant's submission supportive of inventive step that allowing exposure of the cards to atmosphere until sealing takes place in the carrier and test device processing subsystem was not to be expected. Since exposure was not to be expected, the appellant's submission also counters the remark of the examining division concerning support for its decision seen in decision T0505/96, where the Board of Appeal indicated that the simplification of existing complicated technology in situations in which the advantages of the simplification could be expected must be considered to be part of the normal work of the person skilled in the art. In the present case no support is given to the decision under appeal because here - in contrast with the situation in T0505/96 - the specific way the simplification is achieved could not be expected for the reasons given in point 3.2 above.

3.4 In view of the foregoing, although speculation might be made about what changes the skilled person could have made to simplify the system of document D1 by removing components, for example diluting and pipetting, and rearranging the transport system, this would be no more than speculation, no convincing argument for lack of inventive step of the specific system claimed derives from a combination of the teachings of documents D1 and D2.

3.5 Other than documents D1 and D2 there are no further citations in the International Search Report and the

prior art mentioned in the introductory portion of the description does not come closer to the subject matter claimed and thus does not affect the view of the board on inventive step advanced above.

3.6 Accordingly, the board is satisfied that the subject matter of claim 1 can be considered to involve an inventive step.

4. Claim 13 - Clarity

The objection of the examining division that there is no definition concerning the carriers having slots has been met in amended claim 13 by recitation of the feature "...slots formed in the said carrier allowing the said carrier's location to be monitored continuously."

Claim 13 - Inventive Step

Since the method claim recites, amongst other things, that the carrier and test device processing subsystem moves the carrier to a module automatically sealing the test sample devices, its subject matter can be considered to involve an inventive step for reasons corresponding to those given for system claim 1 in section 3 above.

5. Procedure

In view of the foregoing and since the board sees no other bar to grant of a patent, the board considers it appropriate to exercise powers within the competence of the first instance and order grant of a patent.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to grant a patent in the following version:

Description:

Pages 1-6 and 8-47 as originally filed.
Page 7 including three attached insertion pages received during oral proceedings of 4 May 2012.

Claims:

No. 1-17 received during oral proceedings of 4 May 2012.

Drawings:

Sheets 1/34-34/34 as originally filed.

The Registrar:

The Chairman:



M. Kiehl

A. Klein

Decision electronically authenticated