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**Datasheet for the decision  
of 27 September 2016**

**Case Number:** T 0485/11 - 3.5.05

**Application Number:** 00964617.5

**Publication Number:** 1226539

**IPC:** G06F19/00

**Language of the proceedings:** EN

**Title of invention:**

Method and means for data management in a laboratory

**Patent Proprietor:**

Diesse Diagnostica Senese S.p.A.

**Opponent:**

Orgentec Diagnostika GmbH

**Headword:**

Identification of sample containers/DIESSE

**Relevant legal provisions:**

EPC Art. 56

**Keyword:**

Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
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Case Number: T 0485/11 - 3.5.05

**D E C I S I O N**  
**of Technical Board of Appeal 3.5.05**  
**of 27 September 2016**

**Appellant:** Diesse Diagnostica Senese S.p.A.  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 23 December  
2010 revoking European patent No. 1226539  
pursuant to Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chair** A. Ritzka  
**Members:** P. Cretaine  
D. Prietzel-Funk

## **Summary of Facts and Submissions**

I. This appeal is against the decision of the opposition division, dispatched on 23 December 2010, to revoke European patent No. 1 226 539. The opposition was based on the grounds of Article 100(a) and (c) EPC and the patent was revoked for lack of inventive step (Article 56 EPC) of the subject-matter of the claims as granted, having regard to the disclosure, in combination, of

E1: US 3 831 006,

E2: WO 96/01693, and

E4: WO 99/41014.

II. The proprietor's notice of appeal was received on 28 February 2011 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 26 April 2011. The proprietor (appellant) requested that the decision of the opposition division be set aside and that the patent be maintained as granted. Oral proceedings were requested on an auxiliary basis.

III. The respondent (opponent) confirmed by letter dated 1 July 2011 its request that the patent be revoked for lack of inventive step of the granted claims and thus that the appeal be dismissed. Oral proceedings were requested on an auxiliary basis.

IV. A summons to oral proceedings was issued on 9 June 2016. In an annex to this summons, the board stated that it was common ground in the submissions of the parties that E1 represented the closest prior art, and

it listed the points to be discussed during the oral proceedings. Further the board expressed its preliminary view that the feature of placing the identification code on a container at the time of production or packaging did represent a technical feature, contrary to the view taken by the opposition division.

- V. By letter dated 18 July 2106, the respondent expanded upon its arguments regarding lack of inventive step of the claims as granted.
- VI. By letter dated 23 August 2016, the appellant maintained its main request, filed a new set of claims according to a first auxiliary request and provided further arguments in respect of inventive step.
- VII. By letter dated 20 September 2016, the respondent provided arguments as to lack of inventive step of the main and first auxiliary requests.
- VIII. Oral proceedings were held as scheduled on 27 September 2016. The appellant requested that the decision under appeal be set aside and that the patent be maintained unamended, or alternatively in amended form on the basis of the claims according to auxiliary request 1 filed with the letter dated 23 August 2016. The respondent requested that the appeal be dismissed, and that auxiliary request 1 submitted with the letter dated 23 August 2016 not be admitted into the appeal proceedings.

At the end of the oral proceedings, the decision of the board was announced.

- IX. Claim 1 of the main request reads as follows:

"A method for data management in an analytical laboratory,  
comprising the steps of:  
. providing a plurality of containers for the laboratory analysis of biological specimens, each container being associated with a unique identification code, placed on the container at the time of the production or packaging thereof;  
. by means of a central computer, associating a patient code with a patient to be subjected to analysis;  
. for each container used for said patient, generating in a data processing system a combination of said patient code and said identification code of the corresponding container;  
. carrying out, by means of at least one analyzer, at least one analysis on the container or containers used for said patient, the analyzer entering the results of said analysis, combined with the identification code of the container or containers, into the data processing system,  
wherein said identification code contains additional data relating to the type of analysis for which said container is intended, and wherein the analyzer receiving a container reads the identification code and checks that the type of analysis for which the container is intended corresponds to the analysis which the analyzer is to carry out."

The main request comprises a further independent claim (claim 12) for a corresponding system.

Considering the outcome of the decision, the details of the first auxiliary request do not need to be mentioned.

## **Reasons for the Decision**

1. The appeal is admissible.
2. Main request - Article 56 EPC
  - 2.1 It was common ground in the written and oral submissions of both the appellant and the respondent that E1 represents the closest prior art to the subject-matter of the granted claims. Both parties also agreed that, as stated in the decision under appeal, the subject-matter of claim 1 differs in substance from the disclosure of E1 in that:
    - 1) the identification code is placed on each container at the time of production or packaging of said container,
    - 2) said identification code is composed of two fields,
    - 3) the first field represents an identifier of the container and the second field represents additional data relating to the type of analysis for which said container is intended, said data being read by an analyser receiving said container to check that the type of analysis for which the container is intended corresponds to the analysis which the analyser is to carry out.
  - 2.2 Technical character of feature 1)

The opposition division took the view that the labelling of a sample container at the stage of production or packaging was merely an administrative measure devoid of any technical aspects and should thus not be taken into consideration in assessing inventive

step, because this feature did not solve the technical problem of avoiding label misplacement. The respondent also challenged the technical character of feature 1) since it was irrelevant when the identification code was applied to the container as long as it was applied before it was filled with the biological material that was to be analysed.

The board however notes that, since the identification code contains data relating to the type of analysis for which the container is intended, placing it at the time of production or packaging can prevent a medical operator at the time of use from choosing a container which could be inappropriate for the intended analysis of a patient sample. Therefore, at least for this reason, feature 1) can be considered as a technical feature solving the technical problem of avoiding label misplacement with respect to the kind of container to be used for a given type of analysis. The appellant has also plausibly argued that placing a unique code on a container at the time of production may prevent the same identification code from being assigned to two different containers due to a failure in the medical laboratory information system or an error by a medical operator. Further, the appellant has stressed that having a unique identification code from the time of production enables containers to be uniquely identifiable on a large geographical basis and not solely within a single medical laboratory.

For these reasons, the board judges that feature 1) has technical character in the context of the application.



### 2.3 Prior art

E1 discloses a patient sample identification system wherein a patient entering a hospital is associated with a unique random number  $x$ . When samples are taken from the patient, a hospital technician uses several containers and attaches to them, at this time of use, labels each encoded with the unique random number  $y$ . The number combination  $x/y$  is then stored in a memory such that the results of further analysis of the container contents can be correlated to the patient's identity. There is no disclosure in E1 of the identification code comprising an indication of the type of analysis for which the container is intended, let alone of the analyser reading the identification code for checking the type of analysis for which the container is intended.

E2 discloses medical sample containers having labels with bar-codes identifying both the patient's sample and the type of analysis to be performed on it. E2 does disclose that the analyser reads the bar-code to check which type of analysis has to be performed on the sample in a container. However, the type of analysis indicated by the bar-code is related to the specific sample to be analysed, not to the type of analysis for which the container is intended and which was set at the production or packaging time, as defined in claim 1.

E4 discloses a method for labelling medical sample containers at the time of production with a code which makes it possible to control the analysis of their contents. E4 does mention (see page 4, line 19) that the code may indicate the intended purpose or use of the container. It does not however disclose that the

intended use is related to the type of analysis (it may well be the intended geographical or gender use for instance). It does thus a fortiori not disclose that the analyser checks that the type of analysis for which the container is intended corresponds to the analysis which the analyser is to carry out.

2.4 The technical effects of the distinguishing features of claim 1 identified in point 2.1 with respect to E1 as closest prior art are that:

- the container identification code is unique to each container and not defined by the laboratory information system,
- the type of analysis for which the container is intended may be checked by the analyser as well as by the medical operator who selected the container.

It was common ground during the oral proceedings that there is no synergistic effect between the distinguishing features of claim 1 relating on the one hand to the uniqueness of the identification code placed at the time of production, leading to the first technical effect, and on the other hand to the indication of the type of analysis contained in the identification code, leading to the second technical effect. Therefore, two partial technical problems can be formulated:

- how to generate a unique patient/container association which has high reliability,
- and how to avoid performing a wrong analysis on the content of a given container.

The respondent has argued, and the board agrees, that E4 addresses the first partial problem (see page 1, lines 22 to 24 and page 3, lines 1 to 3) and discloses the same solution as claim 1, i.e. placing a unique

identification code on the container at the time of production (see page 3, lines 4 to 14, page 4, lines 14 to 19 and page 7, lines 4 to 6). Therefore, the feature of placing a unique identification code at the time of production of the container cannot contribute to inventive step of the subject-matter of claim 1.

As to the second partial problem, the respondent has presented two alternative lines of argumentation, one based on E1 alone, the other based on a combination of E1 with E2.

First, according to the respondent, document E1 itself discloses at column 14, lines 15 to 23 a check of the type of analysis ("tests to be performed") by the analyser, based on a combined patient's identity/ container's identity code ("bulk quantity identity"). Further, the passage at column 3, lines 33 to 37 teaches that the code could be placed on the container before the sample is put inside. The board however is not convinced by these argument since the "tests to be performed" mentioned in E1 do not simply represent a type of analysis in the sense of claim 1. In E1, it is the medical operator which decides to use a particular container for a particular type of analysis, and the labelling of the container with an identification code indicating the type of analysis to be performed reflects the choice of the medical operator in that respect, not the type of analysis for which the container is intended. The skilled person would thus not find in E1 a solution as defined in claim 1 for solving the second partial problem.

Secondly, the respondent has pointed out that the passages from page 3, line 27 to page 4, line 1, from

page 8, line 24 to page 9, line 2 and from page 9, line 27 to page 10, line 2 in E2 indicate that the analyser checks which test is to be performed based on a bar-code label previously placed on the container. The respondent then argued that the skilled person would find in these passages of E2 a hint to code the type of analysis at the time of production of the container. However, in the board's view there is no disclosure in E2 that the bar-code label is placed at the time of production or packaging of the container. More importantly, the whole disclosure of E2 (see in particular page 2, lines 7 to 10, page 6, lines 1 to 3, page 15, lines 18 to 21, page 18, lines 22 to 26, claim 7) is directed to the manufacturing of containers suitable for labelling by the user, i.e. the medical operator, using standard bar-code labels. The mere fact that a bar-code label identifies both the test sample and the test to be performed shows that it is issued when the container is used, not when it is produced. Therefore, a combination of E1 and E2 would not lead the skilled person to the solution of claim 1 for the second partial technical problem.

Thus, the board judges that the subject-matter of claim 1 as granted, and of corresponding independent system claim 12, involves an inventive step having regard to the disclosure of E1, E2 and E4.

3. Since the appellant's main request is allowable, there is no need for the board to consider the appellant's auxiliary request.

**Order**

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

1. The decision under appeal is set aside.
2. The patent is maintained unamended.

The Registrar:

The Chair:



K. Götz-Wein

A. Ritzka

Decision electronically authenticated