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D E C I S I O N
of 18 April 2006

Case Number: T 0962/02 - 3.4.02

Application Number: 98907723.5

Publication Number: 0968434

IPC: G01N 35/02

Language of the proceedings: EN

Title of invention:
Laboratory in a disk

Applicant:
Burstein Technologies, Inc. et al

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54(2), 54(3), 84, 123(2)

Keyword:
"Conciseness (yes - after amendment)"
"Extended subject-matter (no - after amendment)"
"Novelty (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 0962/02 - 3.4.02

D E C I S I O N
of the Technical Board of Appeal 3.4.02
of 18 April 2006

Appellant: Burstein Technologies, Inc.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 17 April 2002
refusing European application No. 98907723.5
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: A. G. Klein
Members: F. J. Narganes-Quijano
J. H. P. Willems

Summary of Facts and Submissions

I. The appellant (applicant) has lodged an appeal against the decision of the examining division to refuse European patent application No. 98 907 723.5 filed as International application No. PCT/US98/04377 and published with the International Publication No. WO98/38510.

II. In the decision under appeal the examining division referred to the following documents:

D1: WO-A-9609548

D2: EP-A-0417305

D11: WO-A-9721090

and found that the sets of claims amended according to the requests then on file did not comply with the requirements of the EPC. The examining division held in particular that the varying scope of the plurality of independent claims of the main request did not comply with the requirements of clarity and conciseness of Article 84 and Rule 29(2) EPC, that the claim 1 according to an auxiliary request did not define novel subject-matter over the disclosure of documents D1, D2 and D3 within the meaning of Articles 54(1), (2) and (3) EPC, and that the amendments to claim 1 according to a further auxiliary request did not comply with the requirements of Article 123(2) EPC.

III. With the statement setting out the grounds of appeal the appellant filed an amended set of claims and requested that the decision under appeal be set aside and a patent be granted on the basis of the amended set of claims.

IV. In response to a telephone consultation with the rapporteur, the appellant filed by letter dated 20 March 2006 a new set of claims 1 to 10 and amended description pages 1, 2, 2a, 3, 4, 7 and 26 replacing the corresponding application documents of the application as published.

Claim 1 according to the present request of the appellant reads as follows:

"An optical disk (10) to be read by an optical reader comprising:

- a sample entry port (14; 24, 25, 26);
- a first optically readable sector (11) located to be optically read from a first side of said disk (10);
- assay means (15, 16, 17, 19) located in said first sector (11) and being provided to bind an analyte suspected of being in a sample introduced through said port (14; 24, 25, 26) to a predetermined location in said sector (11);
- a second optically readable sector (12) located to be optically read from said first side of said disk (10);
- optically readable software readable by said optical reader provided in said second sector (12) and for directing the operation of an information processor during the optical reading of the first optically

readable sector (11) to determine the presence or absence of the analyte; and

- said first (11) and second (12) sectors being provided to be accessible to said reader for a sequential reading of said software and the presence or absence of an analyte at said location by said reader."

Claims 2 to 10 are dependent claims all referring back to claim 1.

V. The arguments of the appellant in support of his requests are the essentially the following:

Software refers to programs that can be used with a computer system, and programs are sequences of coded instructions fed into a computer and enabling it to perform specified logical and arithmetical operations on data (Collin's English Dictionary, William Collins, 1979, London, pages 1383 and 1168). The black bar in the disc of document D1 constitutes an angular calibration marking for the inspection system and its function is merely to provide a reference position to determine the position of the light detector relative to the disc. Thus, the black bar does not provide instructions to a computer or to a processor and consequently does not constitute software.

The disc of document D2 includes information formats. Formats, however, refer to arrangements of data on a magnetic tape, paper tape, etc. to comply with a computer's specific input device, and data is the information operated on by a computer program (Collin's English Dictionary, *supra*, pages 570 and 379). Thus, the information formats referred to in document D2

constitute data to be used by the analysis apparatus and in particular by the information processor and, as shown by the examples of format information given in the document, this data does not constitute software as claimed.

Document D11 emphasizes that the area of the disc on which the data is written is on the side opposite to the wet chemistry side holding the various microsystem components. Thus, the document cannot anticipate the claimed invention.

The diagnostic assay of the invention includes the software for carrying out the individual protocols for the analysis, so that the user does not have to worry about selecting the correct program or protocol in the information processor to operate the diagnostic assay. The skilled person had no teachings available to him which would suggest the invention.

Reasons for the Decision

1. The appeal complies with the requirements mentioned in Rule 65(1) EPC and is therefore admissible.
2. *Clarity and conciseness - Article 84 and Rule 29(2) EPC*

The set of claims amended according to the present request of the appellant contains a single independent claim and therefore overcomes the objections of lack of clarity and conciseness (Article 84 and Rule 29(2) EPC) raised by the examining division in its decision with regard to the varying scope of a plurality of

independent claims of one of the requests then on file. In addition, the Board is satisfied that the claims amended according to the present request of the appellant comply with the requirements of Article 84 EPC.

3. *Support in the original disclosure - Article 123(2) EPC*

The features objected under Article 123(2) EPC by the examining division in its decision have been omitted in the application documents amended according to the present request of the appellant. In addition, the Board is satisfied that the amendments to the application documents according to the present appellant's request do not extend beyond the disclosure of the International application as published (Article 123(2) EPC). In particular, claim 1 is based on claims 1 and 3 as published together with the passages on page 2, lines 9 to 12, page 3, lines 14 and 15, page 7, lines 6 to 11 and 18 to 21, and page 12, lines 6 to 11 of the description as published, and dependent claims 2 to 10 are respectively based on claims 6 to 9, 11, 10 and 12 to 14 as published. In addition, the description has been brought into conformity with the invention as defined in the claims (Article 84 and Rule 27(1) (c) EPC) and the pertinent prior art has been appropriately acknowledged in the introductory part of the description (Rule 27(1) (b) EPC).

4. *Novelty - Articles 52(1) and 54(1), (2) and (3) EPC*

4.1 Document D11 has been considered by the examining division as constituting prior art within the meaning of Article 54(3) EPC. The document discloses a rotatable platform in the form of a disc, comprising on one of its sides sample inlet ports and assay components for the manipulation and the analysis of a sample containing an analyte (page 5, lines 1 to 27, page 8, line 32 *ff.*, page 12, line 12 *ff.*, and page 38, line 27 *ff.*). The document also discloses a device for monitoring the operations carried out in the assay components and for optically detecting and reading the analytical results in the assay components (page 5, lines 16 to 20, page 9, lines 21 to 28, and page 28, line 11 *ff.*). The document further specifies optically readable software data stored in the disc for controlling the detection operation of the device (page 6, lines 5 to 7, page 29, lines 7 to 14, page 41, lines 7 to 20, page 42, lines 5 to 10, and page 44, line 20 *ff.*).

Document D11 also specifies that the assay components in the disc are readable by a conventional CD laser system (page 59, lines 14 to 21) and that the control programming is encoded on the disc according to conventional compact disc technology (page 58, lines 10 to 15). In view of this disclosure, the examining division concluded in the decision under appeal that, since the disk is of a transparent material (page 17, line 23 *ff.*), both the assay components and the software data could be read from the same side of the disc. However, all the claims (see in particular independent claims 1 to 3) as well as the description

of the document (see in particular page 1, lines 18 to 21, page 11, lines 15 to 19, and page 29, lines 4 to 6) refer consistently to the software data being stored on the side of the disc opposite the side containing the assay components, and there is no disclosure that the assay components and the software data could both be optically read from the same side of the disc. The use of conventional compact disc technology for the software data would rather indicate that said data is read from the side of the disc on which the data is encoded and that the assay components on the opposite side of the disc would not generally be readable from the data side.

In view of the above, there is no unambiguous disclosure in document D11 that both the assay components and the software data in the disc can be sequentially optically read by an optical reader from the same side of the disc as required by the subject-matter of claim 1. For this reason at least, the claimed subject-matter is novel over the disclosure of document D11 (Articles 52(1) and 54(3) EPC).

- 4.2 Document D1 discloses a rotatable disc (Figure 1 and page 10, line 20 *ff.*) including assay means arranged on a first side of the disc to bind an analyte in a sample to a predetermined location (page 11, lines 5 to 20), the sample material being detected by means of an optical reader (page 11, line 21 *ff.*).

The document further specifies position information digitally encoded in the disc (page 14, lines 5 to 18) and readable by means of a scanning light beam (page 17, lines 4 to 11). However, the position information

consists of position codes imprinted at discrete locations of the disc (page 14, lines 7 to 15), or of address information distributed according to a track/sector arrangement (page 14, lines 15 to 18). Thus, the information encoded in the disc only constitutes a reference for determining the location of the scanning light beam relative to the disc surface (page 4, lines 2 to 26, and page 6, lines 10 to 17) and does not constitute software as claimed. The same conclusion applies to the disclosure in document D11 relating to the provision of calibration markings or tracks on the disc (page 8, lines 15 to 19, and page 21, line 11 *ff.*).

In its decision the examining division interpreted the term "software" as any encoded information and concluded that the information encoded in the disc of document D1 also constituted software. However, as submitted by the appellant, software generally relates to instructions for performing specific operations on data and the information specified in document D1 as being encoded in the disc constitutes at the most data, but not software within the proper meaning of the term. Consequently, the Board cannot follow the examining division's contention in this respect.

In view of the above, document D1 fails to anticipate the subject-matter of claim 1 (Articles 52(1) and 54(2) EPC).

- 4.3 Document D2 discloses a rotatable disc comprising on one of its sides assay means for carrying out an analysis of an analyte present in a sample (column 5, line 38 *ff.*, and column 9, line 19 *ff.*) previously

applied to the assay means through sample drop portions on said side of the disc (column 6, lines 6 to 19 and column 7, lines 28 to 33). Light reflected by the assay means is detected by an optical head and processed to detect the analyte (column 8, lines 2 to 43 and column 9, lines 48 to 52). A device comprising a central processing unit controls, among others, the processing of the detected light in accordance with a program stored in a memory unit (column 8, line 44 to column 9, line 9). The disc further includes information formats (column 11, line 55 *ff.*) optically read by a reading head (column 12, lines 21 to 28 and 52 to 58), and the read information is then said to be used to control the different steps of the sample analysis in the disc (Figure 1, column 12, lines 17 to 20 and column 13, line 38 *ff.*).

The document further specifies that the information formats are on either side or on both sides of the disc (column 11, line 55 to column 12, line 3, and column 12, lines 29 to 34). Consequently, the document discloses variants in which the information formats and the assay means can be optically detected from the same side of the disc.

However, the document specifies that the program for operating the processing unit is stored in a memory unit external to the disc (Figure 1 and column 8, line 44 to column 9, line 9) and is silent as to the possibility of including in the disc the corresponding software required to direct the operation of the processing unit.

The argumentation of the examining division in the contested decision that the information formats qualify as software also fails to persuade the Board. According to document D2, the information encoded in the information formats relates to different data required for carrying out the sample analysis test such as the date of manufacture, test items, rotation speed and positioning of the disc, wavelength of the detecting light, grades of the reagents, etc. (column 12, lines 4 to 16). This information only relates to parameter values and data that is then fed as input data to, and operated on by the processing unit (column 13, lines 38 to 52) according to the program stored in the external memory unit but, as submitted by the appellant, does not constitute software for reasons analogous to those put forward in point 4.2 above with regard to the disclosure document D1.

Therefore, claim 1 also defines novel subject-matter over the disclosure of document D2 (Articles 52(1) and 54(2) EPC).

4.4 After due consideration of the remaining documents in the file constituting prior art within the meaning of Article 54 EPC, paragraphs (2) and (3), the Board is also satisfied that none of these documents anticipates the subject-matter of claim 1 (Article 52(1) and 54 EPC).

5. *Inventive step - Article 52(1) and 56 EPC.*

The issue of inventive step was not addressed in the decision under appeal. Notwithstanding, in view of the documents on file, the Board is satisfied that the

claimed subject-matter involves an inventive step over the available prior art (Articles 52(1) and 56 EPC). In particular, none of the disclosures on file to be taken into account for the assessment of inventive step (Article 56 EPC, second sentence) teaches or suggests encoding in an optically readable assay disc as that disclosed in document D1 or D2 optically readable software for directing the operation of optically detecting an analyte in the assay disc as claimed, nor the effects achieved therewith, namely minimizing errors when performing the specific assay in the disc and enabling non-qualified persons an accurate analysis of a sample (page 2, lines 23 to 26 and page 7, lines 8 to 11 of the description as published).

6. Claims 2 to 10 are all dependent claims referring back to claim 1 and the conclusions in points 4 and 5 above also apply to them (Articles 52(1), 54 and 56 EPC).

7. In view of the above conclusions, the decision under appeal is to be set aside. In addition, being satisfied that the application as amended according to the present request of the appellant and the invention to which it relates meet the requirements of the EPC (Article 97(2) EPC), the Board, in accordance with Article 111(1) EPC, considers appropriate to exercise favourably the power within the competence of the examining division to 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 on the basis of the following application documents:
 - description pages 1, 2, 2a, 3, 4, 7 and 26 filed with the letter dated 20 March 2006, and pages 5, 6 and 8 to 25 of the International application as published,
 - claims 1 to 10 filed with the letter dated 20 March 2006, and
 - drawing sheets 1/14 to 14/14 of the International application as published.

The Registrar:

The Chairman:

M. Kiehl

A. G. Klein