

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen
(D) No distribution

D E C I S I O N
of 29 November 2004

Case Number: T 1184/02 - 3.4.2

Application Number: 94925997.2

Publication Number: 0716739

IPC: G01N 21/03

Language of the proceedings: EN

Title of invention:

Fluid dose, flow and coagulation sensor for medical instrument

Applicant:

Roche Diagnostics Corporation

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 56

Keyword:

"Claim 1 - inventive step (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 1184/02 - 3.4.2

D E C I S I O N
of the Technical Board of Appeal 3.4.2
of 29 November 2004

Appellant: Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46256 (US)

Representative: Knauer, Martin, Dr.
Roche Diagnostics GmbH
Patentabteilung
Sandhofer Straße 116
D-68305 Mannheim (DE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 31 July 2002
refusing European application No. 94925997.2
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: A. G. Klein
Members: M. A. Rayner
M. J. Vogel

Summary of Facts and Submissions

I. In its appeal filed on 27 September 2002, the appeal fee being paid on the same date, the applicant appealed against the decision of the examining division of 31 July 2002 refusing European patent application number 94 925 997.2, (published application W095/07452), the statement of grounds for appeal being filed on 27 November 2002. The patent application concerns a combination of a blood coagulation determining instrument and a cuvette.

II. In its decision, the examining division decided that the subject matter of claim 1 before it did not involve an inventive step with respect to document

D3: US-A-5 110 727.

The examining division considered as novel over closest prior art document D3, that the heater contains a tile and the radiation reflective surface is attached to the heater. The subject matter of claim 1 could not be considered inventive because it was obvious to the skilled person that tiles may be used as heater material for maintaining a constant temperature, the applicant having provided no information to the contrary. The problem associated with placement of the radiation reflective surface may be regarded as the attachment of the reflective surface to an alternative element of the device. The problem of attaching the radiation reflective surface to the heater instead of the cuvette amounts to an obvious selection of one of two choices, which would have been made without inventive step. While the applicant is right about the

disadvantage of document D3 in having to attach a radiation reflective surface to all of the cuvettes, the feature claimed is still an obvious design feature. Having the problem of attaching the radiation reflective surface to an element which is different to the exchangeable cuvette, it is obvious to attach it to the heater placed next to the cuvette.

III. Case of the Appellant

In the claims, references to the word "tile" have been changed to "heater plate".

(a) *Requests*

The appellant requests that the decision under appeal be set aside and that the patent be granted on the basis of the documents specified in the letter dated 10 November 2004. A request is made on an auxiliary basis for oral proceedings.

(b) *Arguments*

The position of the appellant is that the prior art, especially document D3, does not disclose a heater assembly with a heater plate, which includes a reflective surface, but only a heater without any optical elements and a separate optical system. Thus the base of each test element has to be equipped with a reflective surface. The combination of two functions in the heater assembly results in an important reduction in cost and space saving.

(c) *Independent claim*

The independent claim upon which the request of the appellant is based is worded as follows:

"In combination, an instrument (100) for determining a coagulation characteristic of blood, a blood fraction or a control comprising a radiation-reflective surface (194), a first source (244) for irradiating the surface (194), and a first detector (242) for detecting radiation reflected from the surface (194), a heater (183) comprising an electrically resistive foil (182) for maintaining the blood, blood fraction or control at a desired temperature, means (180) for mounting the heater (183) adjacent the surface (194), means (322) for providing power to the heater (183) and means (188) for monitoring the surface temperature and for feeding the monitored temperature back to the means (322) for providing power to the heater (183), the surface (194) comprising a first radiation reflective surface of a heater plate (192), the heater plate (192) further comprising a second surface opposite the first surface (194) thereof, and means for mounting the electrically resistive foil (182) to the second surface of the heater plate (192), and a cuvette (101) for holding a sample of the blood, blood fraction or control the coagulation characteristic of which is to be determined, the cuvette (101) having two opposed walls (506, 508) substantially transparent to the source (244) radiation and reflected radiation, the first source (244) and first detector (242) being disposed adjacent a first one (508) of said two opposed walls (506, 508) and the radiation reflective surface (194) being disposed

adjacent a second (506) of said two opposed walls (506, 508)."

Reasons for the Decision

1. The appeal complies with the provisions referred to in Rule 65(1) EPC and is therefore admissible.

2. *Article 123(2) - Amendments*

The subject matter of the claims derives for example from the statement of claim as originally filed. The term "heater plate" is supported by the disclosure of, for example line 34 on page 10 of the application as originally filed.

3. *Patentability*

3.1 Novelty of the subject matter of claim 1 was not challenged by the examining division and is not in doubt because there is no disclosure of a radiation reflective surface of a heater plate. According to document D3, a radiation reflective surface is associated with the reaction slide. Therefore, the subject matter of claim 1 is novel in the sense of Article 54 EPC over the disclosure of document D3.

4. *Inventive Step*

4.1 With reference to reaction slides, document D3 teaches that a reflective layer can be used to enhance light transmission. Metallised films may be heat sealed or glued with an adhesive (e. g. cyanoacrylates) to the

base and cover of the reaction slide. Metallised glass may also be utilised (see column 35, line 39 et seq.). Concerning the instrument for measuring light scatter or reflectance through a reaction slide cover, Figures 24 and 25 of document D3 show a housing 140 comprising a lower housing 142 and cover 144 resting on or integral with lower housing 142 (see column 36, lines 15 et seq.). From Figures 24 and 25, it can be seen that lower housing 142 is of box like rectangular shape, the sectional view in Figure 25 seeming to show a plate bent three times back on itself to form the box. The top view of Figure 24 shows the reaction slide 1 on the housing 142 to be about a third of and in the middle of its shorter dimension and to extend for most of its longer dimension. A lower end of wall 146 of cover 144 is spaced from the top 148 of lower housing 142 by a distance which is sufficient to allow the reaction slide 1 to be inserted. It is desirable for the spacing between the lower end of wall 146 and the plate 148 to be as low as possible to aid in the exclusion of ambient light. Temperature control is provided for the reaction slide by means of heaters of a thermal control system, illustrated schematically as element 156, shown suspended from inside the cover. One form of such a heater may be a resistive heater strip 157 fastened to the bottom of plate 148.

- 4.2 In contrast with the disclosure of document D3, incorporation of an optical function into the heating assembly as occurs in the subject matter of claim 1 under appeal renders unnecessary separate optical means for performing this function. Therefore, a general problem of simplifying the device is solved leading to cost and space saving, the solution not being suggested

by any of the prior art documents on file. The board therefore concurs with the appellant that an inventive step is involved in the subject matter of claim 1.

4.3 The board disagrees with the approach of the examining division because it amounts to identifying the problem as rearranging the device by attaching the reflective surface to another element of the device and selecting the heater, simply for the reason that this is what the appellant claims. In the board's view, there would have been a number of ways of "attaching to other elements", while having in mind optical and thermal constraints, not to mention mechanical introduction of the slide. An element of hindsight is therefore involved in the approach of the examining division, especially as one should be mindful that any attaching of the reflective surface without involving the reaction slide does not follow the teaching of document D3, so why do it?

4.4 The remaining documents in the file are not more relevant to inventive step of the subject matter discussed in the foregoing than is document D3, thus detailed analysis of their content is not necessary in the context of this decision. On the basis of the file before it, the board thus has not seen a convincing line of argument challenging inventive step.

4.5 Therefore the board is satisfied that the subject matter of the independent claim can be considered to involve an inventive step within the meaning of Article 56 EPC.

5. *Oral Proceedings*

5.1 Since oral proceedings were requested only on an auxiliary basis, the for the appellant positive outcome of the appeal renders such proceedings unnecessary.

6. *Further Procedure*

6.1 The board having satisfied itself that the application and the invention to which it relates meet the requirements of the Convention, grant of a patent can be envisaged (Article 97(2) EPC).

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 grant a patent on the basis of the following documents:

Description

- (a) pages 1,3-27,29,32 as published
- (b) pages 2, 28, 30 and 31 as filed with the letter of 10 November 2004

Claims

1-9 filed with the letter of 10 November 2004

Drawings

Sheets 1/17-17/17 as published.

The Registrar:

The Chairman:

P. Martorana

A. G. Klein