

Publication in the Official Journal ~~Yes~~ / No

File Number: T 538/91 - 3.4.2

Application No.: 85 308 592.6

Publication No.: 0 184 374

Title of invention: Disposable unitary cytology chamber and filter card for centrifugation of fluid samples and method of making same

Classification: G01N 1/28, B04B 5/04

D E C I S I O N
of 30 June 1992

Applicant: Whale Scientific Inc.

Headword:

EPC Articles 84, 54,56

Keyword: After amendment: clarity (yes); novelty (yes); inventive step (yes)



Case Number : T 538/91 - 3.4.2

D E C I S I O N
of the Technical Board of Appeal 3.4.2
of 30 June 1992

Appellant : Whale Scientific Inc.
4945 Monaco Street
Commerce City
Colorado 80022 (US)

Representative : Jack, Bruce James
FORRESTER & BOEHMERT
Franz-Joseph-Strasse 38
W - 8000 München 40 (DE)

Decision under appeal : Decision of Examining Division of the European
Patent Office dated 8 February 1991 refusing
European patent application No. 85 308 592.6
pursuant to Article 97(1) EPC.

Composition of the Board :

Chairman : M. Chomentowski
Members : C. Black
C. Holtz

Summary of Facts and Submissions

- I. European patent application No. 85 308 592.6 (publication No. 0 184 374) was refused by the Examining Division on the grounds that the subject-matter of the valid Claim 1 did not involve an inventive step having regard to the disclosure in, inter alia,

D1 = US-A-4 391 710.

In particular, the Examining Division considered that, starting from the assembly known from D1 comprising a chamber supporting a filter card and a superposed microscope slide, an obvious problem would be that the filter card could slip during use of the assembly, i.e. during centrifugation, and that an obvious solution to this problem would be found by the skilled person in his general technical knowledge and would consist in providing glue between the filter card and the flange surface of the chamber thereby arriving at the device of Claim 1.

D2 = US-A-4 357 240 and

D3 = US-A-4 265 762

had also been taken into consideration during the examination procedure.

The Examining Division, however, expressed the opinion that the independent method claim would be allowable having regard to the available prior art.

- II. The Appellant (Applicant) filed an appeal against this decision.
- III. In two communications, the Board of Appeal expressed objections concerning lack of clarity and lack of novelty

of a submitted main claim. Oral proceedings, requested auxiliarily by the Appellant, were held, at the end of which he filed an amended set of Claims 1 to 12 and patent specification and submitted a main request, that the decision under appeal be set aside and that a patent be granted on the basis of said claims and specification, and an auxiliary request with an amended main claim as had been submitted with the written Statement of Grounds of Appeal.

IV. Claims 1, 7 and 8 of the main request read as follows:

"1. A unitary disposable cytology sample chamber and filter card unit adapted for use in the analysis of body fluids, comprising a sample chamber (10) having a liquid sample-receiving funnel (34), a flat solid flange member (30) defining a support surface (30') and a discharge port (36) extending from said funnel (34) and terminating in an opening (37) in said support surface (30'); a filter card (40) overlying said support surface (30') of said flange member and including an opening (42) therein; characterised in that the filter card is permanently affixed to said support surface (30') at locations adjacent to the outer peripheral edges of the flange member with said opening in said card aligned with said discharge port and is thereby integrally united to said support surface and cannot be removed from said support surface without leaving segments of said filter card attached to said support surface at said locations."

"7. A centrifuge having a plurality of holders mounted on a rotating carrier, each said holder having clamping means for releasably receiving a cytology chamber, a filter card and a microscope slide therein, characterised by a disposable unit according to any one of claims 1 to 6 disposed in each said holder to constitute the cytology

chamber and filter card and positioned so that said clamping means releasably clamp said slide in overlying relation to the filter card of the disposable unit."

"8. The method of forming a unitary, disposable sample chamber and filter card unit in which a sample chamber (10) is provided with a liquid sample funnel (34) and a discharge port (36) which communicates between said funnel and an end flange (30), and a filter card (40) is placed in position on said end flange (30) with an opening (42) in said filter card (40) aligned with said discharge port (36), characterised by the steps comprising forming energy directors in the form of protruding ribs (60) on a flat surface (30') of said end flange (30) and applying ultrasonic energy to said end flange whereby to weld said energy directors to said filter card (40)."

Claims 2 to 6 and 9 to 12 are dependent claims.

V. The Appellant submitted the following arguments in support of his main request.

The device known from D1 has a minor drawback concerning the alignment of the different parts of the unit, which can easily be corrected, and two main drawbacks, namely

- (a) prevention of re-use of the unit, i.e. the sample chamber, is not guaranteed, so that the possible spreading of diseases arises, and
- (b) it is difficult to separate the slide from the rest of the unit after use in centrifugation because of the adherence of the filter card to both the slide and the support surface of the chamber.

The idea of affixing permanently the filter card to the support surface is the inventive idea, whereby a plurality of means, for instance the means of the illustrated embodiment, may be used to carry it out into practice. These two major problems are not derivable from D1, and the claimed solution is not derivable from the prior art in this context. On the one hand, for preventing re-use of units, totally different means have been proposed by the prior art; on the other hand, affixing filter material to a part of a unit is known in other technical fields, for solving different problems. The minor problem related to a possible slipping of the filter card is not derivable from D1 and, moreover, the use of glue would not be taken into consideration in this technical field because of the risk of contamination. Therefore, the subject-matter of the main claims is novel and involves an inventive step.

Reasons for the Decision

1. The appeal is admissible.
2. Main request
 - 2.1 Allowability of the amendments
 - 2.1.1 The Board is satisfied that, since especially those amendments concerning the locations where the filter card is permanently affixed to the support surface are based on features which are disclosed in particular in relation with the embodiment illustrated by the figures, the European patent application has not been amended in such a way that it contains subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC).

2.2 Clarity

2.2.1 The Board is satisfied that, since Claim 1 specifies that the filter card is permanently affixed to the support surface (30') of the flange member at locations adjacent to the outer peripheral edges of the flange member and is thereby integrally united to said support surface and cannot be removed from said support surface without leaving segments of said filter card attached to said support surface at said locations, there is no ambiguity about the location and the technical nature of the affixing means which is implicitly necessary to arrive at said result. The Board moreover agrees that the term "filter card" is current and has an accepted meaning in this art, even though the function of the card is not strictly filtration. Therefore, Claim 1 is clear in the sense of Article 84 EPC.

2.3 Novelty

2.3.1 The Board is satisfied that, since no unitary disposable cytology sample chamber and filter card unit comprising all the features of present Claim 1 is known from the documents of the available prior art, the subject-matter of Claim 1 is novel in the sense of Article 54 EPC. Moreover, since a unitary disposable cytology sample chamber and filter card unit according to Claim 1 is not known from the prior art, no centrifuge comprising such disposable units is disclosed in the documents of the available prior art and, thus, the subject-matter of Claim 7 is also novel. It is further to be noted that no method of forming a unitary, disposable sample chamber and filter card unit comprising all the features of Claim 8 is known from the available prior art and that, therefore, the subject-matter of Claim 8 is also novel.

2.4 Inventive step

2.4.1 D1 is the closest prior art document. The unitary disposable cytology sample chamber and filter card unit adapted for use in the analysis of body fluids known from D1 (see column 1, line 67 to column 3, line 49; column 4, line 24 to column 8, line 9; Figures 1 to 4) comprises: a disposable sample chamber having a liquid sample-receiving funnel (43), a flat solid flange member (40) defining a support surface and a discharge port (41) extending from said funnel (43) and terminating in an opening (42) in said support surface; a filter card (39) overlying said support surface of said flange member and including an opening therein; a microscope slide (38) on the filter card.

However, contrary to the device of present Claim 1, in the unit of D1, the filter card is not at all permanently affixed to said support surface let alone at locations adjacent to the outer peripheral edges of the flange member with said opening in said card aligned with said discharge port; therefore, it is not thereby integrally united to said support surface in the manner required by Claim 1.

2.4.2 In the unit known from D1, no means to preclude re-use of the cytology chamber and/or of the filter card is mentioned. However, in the handling of body fluids that could give rise to certain diseases, it is vital that the chamber or filter card should not be re-used after a particular sampling operation (see the patent application, page 2, lines 9 to 28).

2.4.3 Moreover, as credibly argued by the Appellant, in the unit known from D1, after use, when matter has deposited on the

exposed surface of the slide within the opening in the filter card, since the filter card with the liquid it has absorbed may adhere to

- (a) the support surface of the sample chamber and/ or
- (b) the microscope slide,

said filter card may be displaced when being peeled off from the slide, thereby disturbing the deposit on said slide. This is a second drawback of the device of D1.

2.4.4 The unit of Claim 1 intends to provide a solution to the above mentioned problems. The Board is of the opinion that it can be accepted that, as argued by the Appellant, since the filter card in the present patent application (see page 8, lines 9 to 32) is affixed to the support surface with the opening in said card aligned with said discharge port (36), said affixing being firm and permanent whereby any attempt to remove the filter card from the unit will leave substantial segments in surrounding relation to the locations of affixing, this will preclude paper placement and positioning of a fresh filter card over the end flange of the chamber, and re-use of the filter card or assembly will thus be prevented. The Board is also satisfied that, by affixing the filter card permanently to the support surface, the slide will be more easily removed from the rest of the unit, and in particular from the filter card, without disturbing the deposit, even though this advantage is not mentioned in the present application.

2.4.5 Neither the problem of re-use of the unit, nor its solution, are derivable from D1 or from the documents of the available prior art in the relevant technical field. Concerning this problem, it is to be noted that, on the

contrary, D1 (see column 2, lines 15 to 20; column 8, lines 3 to 9) mentions that the holders and the sample chambers may be cleaned and sterilised.

2.4.6 Indeed, the problem concerning the re-use of units including filters is known in other technical fields, in particular in the field of filtering apparatuses. For instance, D2 (see in particular column 2, lines 33 to 38) discloses a unitary disposable unit including a chamber and filter unit, which is adapted to solve this problem but, although D2 (see column 3, lines 17 to 25) specifies that the filter medium (56) can be attached to the disc (44) of the filtration unit (10) by sonic or heat sealing, this is however not mentioned as being related to a measure to preclude re-use of the unit; on the contrary, in said unit, it is the plastic of the body of the unit which should be of the type which is heat degraded so that the filtration unit cannot be sterilised and must be discarded after use. Therefore, the Board is of the opinion that the indications in D2 would not lead to the presently claimed device.

2.4.7 D3 (see column 3, lines 10 to 58; Figure 1) also discloses a filter assembly (10) for use in the filtration of medical treatment liquids, including a strip of porous filter media (12) and first and second enclosure means (14, 16) which are ultrasonically welded to respective surfaces of the filter media, in particular by means of the respective edges (30) and protruding dimples (36, 42) formed in said enclosures. However, D3 (see column 2, lines 10 to 12; column 3, lines 65 to 68) only specifies that the dimples are attached to opposite surfaces of the filter media and thus serve to hold the filter assembly in shape, in particular for giving additional structural integrity to the filter assembly; therefore, this affixing means is not related to the present problems.

- 2.4.8 The Appellant has not denied that the second problem, concerning the risk that the deposit on the slide be disturbed when separating said slide from the filter card after use, was generally known to people skilled in the art; however, he contends that the presently claimed means is not derivable from the relevant prior art. The Board agrees that said means solves both the first problem of preventing re-use and the second problem of protecting the slide sample. Therefore, the Appellant's argument that this associated effect provides a further indication for an inventive step of the claimed device can be accepted.
- 2.4.9 Concerning the means for attaching the filter card to the flange in the unit of D1 (see column 6, lines 3 to 68), which is mentioned as being mechanical means including a clamping element (35), there is no indication in the document that the filter card might slip during use of the unit. On the contrary, D1 (see column 7, lines 1 to 15) mentions that, to facilitate registration of the filter card (39) on the end flange (40) of the unit, said end flange could be provided with a projection (not shown) positioned to engage in the unused hole which is comprised in commercially available filter cards. Thus, the Board is of the opinion that a need for supplementary means for preventing slipping of the filter card is not derivable from D1 and that, should the person skilled in the art be aware for any reason of such a problem, he would find in D1 the means, i.e the mentioned registration means, for arriving at the solution and would not be incited to look for other means, for instance glue, in different technical fields.
- 2.4.10 Therefore, the subject-matter of Claim 1 is not obvious having regard to the available prior art and, thus, it involves an inventive step in the sense of Article 56 EPC.

2.5 The subject-matter of dependent Claim 7, which concerns an apparatus including the device of Claim 1, and the subject-matter of the independent method Claim 8, which defines a method for forming a unit whereby the affixing means is of the type mentioned in Claim 1 but more specifically defined and corresponding to the embodiment illustrated by Figures 2 to 9, also involve an inventive step having regard to the available prior art for the same reasons as Claim 1.

2.6 Therefore, a patent may be granted on the basis of the present European patent application (Articles 52(1) and 97(2) EPC).

3. Auxiliary request

3.1 Since the Appellant's main request is allowable, it is not necessary to consider the auxiliary request.

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 Claims 1 to 12 and the amended description with Figures 1 to 9, as submitted during the oral proceedings.

The Registrar:



P. Martorana

The Chairman:



M. Chomentowski

02631

EB
MCH