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**Datasheet for the decision
of 29 June 2011**

Case Number: T 1352/08 - 3.2.02

Application Number: 02712223.3

Publication Number: 1478278

IPC: A61B 10/00

Language of the proceedings: EN

Title of invention:

A biological fluid collection and sampling container

Applicant:

NOVAMED LTD.

Headword:

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Relevant legal provisions:

EPC Art. 56

Relevant legal provisions (EPC 1973):

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Keyword:

"Inventive step (no)"

Decisions cited:

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Catchword:

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Case Number: T 1352/08 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 29 June 2011

Appellant:

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Representative:

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 6 February 2008
refusing European patent application
No. 02712223.3 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: M. Noël
Members: D. Valle
J. Geschwind

Summary of Facts and Submissions

- I. The appellant (applicant) lodged an appeal by notice filed on 20 March 2008 against the decision of the Examining Division, posted on 6 February 2008, to revoke the European patent application essentially for lack of inventive step of its subject-matter. The fee for the appeal was paid on the same day, and a statement setting out the grounds for appeal was received on 16 June 2008, along with amended sets of claims.
- II. By communication of 21 January 2011, the Board issued a provisional opinion.
- III. The following documents are relevant for the present decision:
- D4: US - A - 4 300 404
D3: US - B1 - 6 315 145.
- IV. Oral proceedings took place on 29 June 2011, during which the appellant withdrew the first to third auxiliary requests submitted with its statement of grounds.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims according to the main request filed on 16 June 2008 or on the basis of the auxiliary request filed during the oral proceedings.

V. The independent claims in suit read as follows:

Independent claim 5 of the main request:

"A method comprising the steps:

providing a urine collection and sampling container (1) comprising: a cup member (2) and a lid assembly (3), said lid assembly being removably mountable to the cup member (2), having an aperture (4) for introducing a dipslide covered with semi solid culture media into the container without removing the lid assembly (3) from the cup member (2), having a cap (9) for closing the aperture (4), and having an additional dedicated sampling means comprising a cannula (10) and a needle member (12) extending into the lower end of the container when the lid assembly (3) is mounted on the cup member (2), wherein the cannula (10) projects through the lid assembly (3) so as to enable to pierce the stopper of an air evacuated tube, collecting a urine sample (20) with the lid assembly (3) being removed from the cup member (2), mounting the lid assembly (3) onto the cup member (2), inserting an evacuated test tube into the cannula (10) such that the needle member (12) pierces the stopper of the test tube and an aliquot of the urine sample is drawn into the test tube to perform a biochemistry test, and opening the cap (9), introducing a dipslide covered with semi solid culture media into the container (1) and dipping the dipslide into the urine sample via the aperture (4) to perform a bacteriological test."

Independent claim 1 of the auxiliary request:

"A urine collection and sampling container (1) comprising:
a cup member (2), and a lid assembly (3) removably mountable to the cup member (2), having an aperture (4) for introducing a sampling means, in particular, a dipslide covered with semi solid culture media, into the container without removing the lid assembly (3) from the cup member (2), having a closure means (5) for closing the aperture (4), having an additional dedicated sampling means comprising a cannula (10) and a needle member (12) extending into the lower end of the container when the lid assembly (3) is mounted on the cup member (2), wherein the cannula (10) projects through the lid assembly (3) so as to enable to pierce the stopper of an air evacuated tube."

VI. The appellant argued as follows:

The steps of the method claim 5 were disclosed on page 1 of the application as filed, which is identical to the PCT publication. Most of these steps were the direct consequence of operating the urine collection and sampling container having the features of the device, as shown by the passages starting from the wording: "In action" on page 4 of the application.

While the original application did not claim any method, independent method claim 5 was introduced during the examination procedure as a fall-back position and in view of possible infringement.

Claim 1 of the auxiliary request differed from the disclosure of D4 in that the container of D4 had no additional aperture for introducing a sampling means for the purpose of performing bacteriological tests and no closure means for closing the aperture.

D3 was not specifically concerned with medical uses and did not address the problem of avoiding contamination of the work bench and the urine sample. The small bores provided in the lid of the container of D3 were not apertures within the meaning of the present application, i.e. not sized for introducing a dipslide test. Therefore, the subject-matter of claim 1 was inventive over a combination of documents D4 and D3. The subject-matter of the claim could only appear obvious in the light of a combination of D4 and D3 on the basis of an ex-post-facto analysis.

Moreover, it had taken more than twenty years to develop the invention, starting from the embodiment of D4. The invention was furthermore commercially very successful.

Reasons for the Decision

1. The appeal is admissible.
2. Main request

Independent method claim 5 of the main request has no basis in the application as originally filed. This already results from the title of the description and from the original claims which were directed

exclusively to a fluid collection and sampling container. The passages referred to by the appellant on pages 1 and 4 to 5 are concerned either with the background of the invention or with the use of the second embodiment of the device illustrated by Figures 2a to 2c. However, a method as such comprising the steps of claim 5 was not the subject of the application as filed and was not presented as being the matter for which protection was sought.

Moreover the use of the device is already covered by the device claims 1 to 4, which confer absolute protection. Therefore, the method claim 5, which includes the steps of using the device, not only appears to be superfluous but also extends the claimed subject-matter as a whole, beyond the content of the application as filed.

A method claim, i.e. a claim in another category, could have been accepted as a replacement for a device claim if there had been no other way to define the device than by its use. This is obviously not the case here, such that the introduction of an additional method claim does not comply with Article 123(2) EPC.

3. Auxiliary request

Using the words of claims 1 at issue, D4 discloses (see Figures 1 to 3 and column 1, lines 12-15) a urine collection and sampling container comprising a cup member 10 and a lid assembly 11, 13 removably mountable to the cup member, having a dedicated sampling means comprising a cannula 17 and a needle member 14, 14b extending into the lower end of the container when the

lid assembly is mounted on the cup member, wherein the cannula projects through the lid assembly, so as to enable to pierce the stopper of an air evacuated tube 15 (see Figure 3 and column 2, lines 12-21). As with the invention, no contamination of the air evacuated tube by droplets from the lid or outside of the collection cup occurs, since it is not necessary in D4 to remove the lid, (see column 2, lines 33-35 and 42-47).

Claim 1 differs from the teaching of D4 first in that the container of the invention has an additional aperture 4 for introducing a sampling means, in particular a dipslide covered with semi solid culture media, into the container without removing the lid assembly 3 from the cup member 2 and secondly in that a closure means 5 is provided for closing the aperture 4. The dipslide is used to perform a bacteriological test by introducing it into the container. However, this sampling means appears in claim 1 as an optional measure ("in particular") and, thus, is not regarded as limiting.

The problem underlying the above-mentioned distinguishing features over D4 is to provide a sampling container enabling both a biochemistry test, using the known evacuated tube methodology, and a bacteriological test. This latter is performed in accordance with the solution as claimed by introducing a sampling means (dipslide) into the remaining sampling fluid without removing the lid, through an additional aperture provided with closure means.

The person skilled in the art looking for a solution to the above problem would consider the teaching of D3 since D3 principally belongs to the same technical field as the invention (see column 1, lines 10-19) and discloses in the embodiment of Figures 19A to 19D a container having a second aperture 172 in addition to a first aperture 174, the second aperture being suitable for introducing into the container different devices such as a sterile loop, a pipette or syringe without removing the lid assembly from the cup member and closure means (plug cover) for closing the respective apertures (see column 9, lines 4-24). It results therefrom that the second aperture may also be adapted to allow the introduction of sampling means such as dipslides since in both D3 and the present application, the size of the additional aperture is not further specified. Also the fact that the apertures are identified as bores in D3 is of no consequence since the terms are equivalent; in the same way as in the present application the aperture 4 is defined both as an aperture and an opening (see paragraph bridging pages 2 and 3 and last paragraph of page 3).

Further, the numerous possibilities of using the container disclosed in D3, also in non-medical fields (see column 3, lines 33-39), suggests a corresponding broad range for the dimensions of the bores.

Contrary to the argument of the appellant, a long-felt need is not a sufficiently strong criterion for reversing findings based on an objective evaluation of the content of the relevant prior art documents. Such secondary indicia may only be of importance in case of doubt as to patentability.

Finally, it should not be given too much weight to the impact of strong sales numbers. In fact, strong sales can be the result of a good marketing strategy or attractive pricing policy. It can be, as a matter of principle, that commercial success depends on the technical features, but that has not been proved in the present case.

Accordingly, the subject-matter of claim 1 of the auxiliary request does not involve an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

G. Magouliotis

M. Noël