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Case Number: T 2036/09 - 3.2.07

Application Number: 03755741.0

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Language of the proceedings: EN

Title of invention:
Collection assembly

Applicant:
Becton, Dickinson and Company

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Inventive step (all requests): no"

Decisions cited:
-

Catchword:
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Case Number: T 2036/09 - 3.2.07

D E C I S I O N
of the Technical Board of Appeal 3.2.07
of 17 January 2012

Appellant: (Applicant)	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417-1880 (US)
Representative:	von Kreisler Selting Werner Deichmannhaus am Dom Bahnhofsvorplatz 1 D-50667 Köln (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted 25 March 2009 refusing European application No. 03755741.0 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: H. Meinders
Members: K. Poalas
E. Dufrasne

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal against the decision of the Examining Division refusing European patent application 03 755 741.0.

II. In its decision, the Examining Division held that the subject-matter of claim 1 is not novel over D1 (EP-A-0 901 821).

III. Oral proceedings before the Board took place on 17 January 2012. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, on the basis of one of the auxiliary requests 1 and 2, all filed with letter dated 15 December 2011, and the auxiliary request 3, filed during the oral proceedings.

IV. The claims 1 of the main request and the auxiliary requests 1 to 3 read as follows (amendments over the main request are depicted in bold):

Main request

"A plurality of container assemblies (80,100) comprising at least a first container assembly (80) and a second container assembly (100), each of said container assemblies in said plurality having an outer container (42) and an inner container (84,104) nested within said outer container (42), said outer containers (42) of each of said container assemblies having substantially identical external dimensions, said inner container (84) of said first container assembly (80)

being configured to define a first volume for said first container assembly, said inner container (104) of said second container assembly (100) being configured to define a second volume for said second container assembly (100), each said container assembly further comprising a closure (70), the closures (70) of said first and second container assemblies being substantially identical,
characterized in that
said second volume is less than said first volume,
and
said first and second container assemblies enable collection of first and second volumes of a fluid with uniform head spaces in the respective container assemblies".

Auxiliary request 1

"A plurality of container assemblies (80,100) comprising at least a first container assembly (80) and a second container assembly (100), each of said container assemblies in said plurality having an outer container (42) and an inner container (84,104) nested within said outer container (42), said outer containers (42) of each of said container assemblies having substantially identical external dimensions, said inner container (84) of said first container assembly (80) being configured to define a first volume for said first container assembly, said inner container (104) of said second container assembly (100) being configured to define a second volume for said second container assembly (100), each said container assembly further comprising a closure (70), the closures (70) of said first and second container assemblies being

substantially identical,
characterized in that
said second volume is less than said first volume,
said inner containers have either different wall thicknesses and the same height, different heights and the same wall thickness or different wall thicknesses and different heights,
said outer containers have identical inner dimensions, and
said first and second container assemblies enable collection of first and second volumes of a fluid with uniform head spaces in the respective container assemblies".

Auxiliary request 2

"A plurality of container assemblies (80,100) comprising at least a first container assembly (80) and a second container assembly (100), each of said container assemblies in said plurality having an outer container (42) and an inner container (84,104) nested within said outer container (42), said outer containers (42) of each of said container assemblies having substantially identical external dimensions, said inner container (84) of said first container assembly (80) being configured to define a first volume for said first container assembly, said inner container (104) of said second container assembly (100) being configured to define a second volume for said second container assembly (100), each said container assembly further comprising a closure (70), the closures (70) of said first and second container assemblies being substantially identical,
characterized in that

said second volume is less than said first volume,
said inner containers have either different wall thicknesses and the same height, different heights and the same wall thickness or different wall thicknesses and different heights,
said outer containers have identical inner dimensions, and
said first and second container assemblies enable collection of first and second volumes of a fluid with uniform head spaces **from the surface of the fluid collected** in the respective container assembl~~y~~**ies to the opening of the outer container**".

Auxiliary request 3

"A plurality of container assemblies (80,100) comprising at least a first container assembly (80) and a second container assembly (100), each of said container assemblies in said plurality having an outer container (42) and an inner container (84,104) nested within said outer container (42), said outer containers (42) of each of said container assemblies having substantially identical external dimensions, said inner container (84) of said first container assembly (80) being configured to define a first volume for said first container assembly, said inner container (104) of said second container assembly (100) being configured to define a second volume for said second container assembly (100), each said container assembly further comprising a closure (70), the closures (70) of said first and second container assemblies being substantially identical,
characterized in that
said second volume is less than said first volume,

said inner containers have different wall thicknesses and the same height,
said outer containers have identical inner dimensions, and
said first and second container assemblies enable collection of first and second volumes of a fluid with uniform head spaces in the respective container assemblies".

V. The appellant argued essentially as follows:

Claim 1 of auxiliary request 3 - Inventive step, Article 56 EPC

The subject-matter of claim 1 differs from the container assembly known from D1 in that it provides at least two different container assemblies, whereby the internal volume of the inner container of one of said container assemblies is less than the internal volume of the inner container of the other container assembly, said inner containers having different wall thicknesses and the same height and the container assemblies having uniform head spaces.

The feature of the uniform head spaces means that the inner containers allow for ("enable") a standard level of the liquid specimen to be achieved.

Dl does not address the feature of claim 1 concerning the provision of uniform head spaces in the respective container assemblies of the multiple container collection to ensure that sample-to-air interaction is minimized and to enable standard testing, i.e. to enable that probes of semi-automated or automated equipments find a uniform level for the liquid specimen's upper surface, independently of the specimen's volume when entering the inner tube and a uniform upper part of the inner tube D1 does not suggest to use the same size outer container with inner containers of different volumes. If more different assemblies were to be provided the skilled person might as well adapt the outer container to the (smaller) size of the inner container.

The person skilled in the art finds also no hint in D1 that the different inner containers should have different wall thickness and the same height.

Reasons for the decision

1. *Preliminary remarks*

1.1 The Board following the definition given on page 2, lines 5 to 7 of the PCT-publication of the present application and concurring with the appellant, considers that the term "head space" defines "the volume between the top of the collected sample and the stopper", the latter being the "closure" as mentioned in the claims.

1.2 Claim 1 according to auxiliary request 3 has the following additional features over claim 1 according to the **main request**:
"said inner containers have different wall thicknesses and the same height,
said outer containers have identical inner dimensions".

1.3 Claim 1 according to auxiliary request 3 differs from claim 1 according to **auxiliary request 1** in that it concerns only the alternative that the inner containers have different wall thicknesses and the same height.

1.4 The Board notes that by following the definition given, see point 1.1 above, and considering the fact that the closures according to these claims are all identical the last paragraph of claim 1 of **auxiliary request 2** defines the same subject-matter as the last paragraph of claim 1 of auxiliary request 3. Therefore, claim 1 according to auxiliary request 3 differs from claim 1 according to the auxiliary request 2 in that it concerns only the alternative that the inner containers have different wall thicknesses and the same height.

1.5 For the reasons given in points 1.2 to 1.4 above, claim 1 according to auxiliary request 3 defines therefore more limited subject-matter over that of claim 1 of the main request and identical subject-matter to only one of the alternatives present in claim 1 of auxiliary requests 1 and 2.

If inventive step cannot be acknowledged for claim 1 of the auxiliary request 3, by definition that applies to the higher ranking requests. In such a case the Board can limit its examination to that request.

2. *Claim 1 of the auxiliary request 3 - Inventive step, Article 56 EPC*

2.1 Disclosure of D1

2.1.1 It is generally well known that biological fluid specimens are routinely taken and analyzed in hospital and clinical situations for various medical purposes, using various medical testing instruments. Since said fluid specimens are usually collected in a standard sized collection tube, the medical instruments used to test the samples are designed to accommodate these standard sized collection tubes, see paragraph [0002] of D1. Some of said specimens are processed or analysed semi-automatically or automatically and they must first be transferred from the collection tube to a sample test tube or cuvette, see paragraph [0004].

In certain situations it is only necessary to obtain a small quantity of a biological fluid specimen. Such small quantities cannot be easily collected in standard collection tubes because the sample level in such containers would not be adequate for retrieval prior to analysis, see paragraph [0005]. Furthermore, small quantities of fluids also have a tendency to significantly evaporate when stored in larger containers, thus concentrating the chemical and enzymatic constituents therein and influencing the measurements, see also paragraph [0005].

2.1.2 In order to avoid low sample levels and the tendency to evaporate due to the presence of large head spaces when obtaining small quantities of biological fluid specimens D1 proposes a specimen collection container assembly 30 comprising an outer container 10a with an inner container 40 nested therein. The internal volume of the inner container is less than the internal volume of the outer container. The outer container is a standard-sized biological fluid collection tube, see abstract, paragraphs [0011] to [0013] and figures 3 to 7. The inner container 40 has an upper cylindrical part 50, a lower cylindrical part 42 with a smaller diameter, and a tapered part 58 connecting said two cylindrical parts. The outer surface 52 of the upper cylindrical part 50 provides frictional fit with the inner wall surface 20a of the outer container l0a, see paragraph [0036]. The container assembly 30 comprises further a closure (cap 60), which is accommodated within the upper cylindrical part 50 of the inner container and extends to the level determined by the circular transition between the upper cylindrical part 50 and the tapered part 58, see paragraph [0037] and figure 7.

The inner container 40 has an internal volume which lies within the range of 1 ml and 3 ml, see claim 9.

With the second circular transition between the tapered part 58 and the lover cylindrical part 42 the inner container **enables** the user to achieve at this line a standard level for the sample liquid. The volume between such a level and the closure is the **headspace** as defined in the claim, in the application and as confirmed by the appellant. That this standard level should be as high as possible, close to the closure, follows from the necessity to be able to use the tubes in standard equipment, requiring a sufficient depth of fluid below such a level, see paragraph [0005], line 56 to line 2 in column 6, and the necessity to have as little influence as possible from the headspace by evaporating the paragraph [0005], column 6, lines 2 to 10.

2.2 Formulation of the technical problem

2.2.1 The subject-matter of claim 1 differs from the individual container assembly known from D1 in that

a_1) it provides at the same time a plurality of at least container assemblies which are different from each other in that the internal volume of the inner container of one of said container assemblies is less than the internal volume of the inner container of the other container assembly,

a_2) the inner containers have different wall thicknesses and the same height.

a_3) the outer containers of these assemblies have identical outer dimensions,

b_1) the closures of these assemblies are identical, and

b_2) the container assemblies have uniform head spaces.

These two sets of distinguishing features actually provide two different technical effects without any synergy so that two partial technical problems have to be established.

2.2.2 By the provision of a plurality of the container assemblies (features a) known from D1, (e.g. in a kit) which differ by the internal volume of the inner containers a wide range of application can be covered than with the singular container assembly known from D1. Different small amounts of biological fluid specimens can thus be collected, according to the circumstances. The problem to be solved is: how to increase the range of application of the container assembly of D1.

While solving this problem it is evident that the outer containers should be identical (feature a_3) and should remain the standard-sized collection tube with which the standard equipment can work without problems, see paragraphs [0002], [0012] and [0013] of D1. The appellant's argument to the contrary therefore cannot hold.

2.2.3 The provision of uniform (= identical volume) head spaces (features b) in the different container assemblies allows the probes of semi-automated or automated equipment to work under uniform conditions, i.e. to find a uniform level for the liquid specimen's upper surface, independently from the specimen's volume, when entering the inner tube and a uniform upper part of the inner tube. The problem to be solved is: how to guarantee the standard test conditions for the different assemblies, while keeping the influence of the headspace on the sample minimal.

2.2.4 Therefore, the person skilled in the art has to solve three technically independent partial problems separately when starting from the independent container assembly known from D1.

2.3 Obviousness of the solutions

2.3.1 Features a_1 and a_2

D1 describes a container assembly of which, the inner container can have a size between 1 and 3 ml.

It is well-known in this field that sample size is determined by the type of test and by the number of tests to be performed on the same sample.

Given the fact that in hospitals and clinical laboratories the taking of samples is preformed by qualified personal using the same equipment, it does not require inventive skills to put at their disposal a set with a plurality of the container assemblies known from D1, which differ from each other only by the volume of the inner containers, to allow for taking the required differently sized samples (feature a_1).

The technical execution of this, starting from the inner container of D1, also does not require inventive skills. The particular choice for maintaining the height of the inner container and changing the wall thickness is in fact one of the obvious ones, as in the mould inspection one merely has to substitute the core for one with a smaller diameter, while maintaining the rest of the mold. Feature a_2) can therefore not support inventive step. For the other obvious alternatives, see point 2.3.4 below.

2.3.2 Feature a_3

The skilled person would do expressly against the teaching of D1 when providing differently sized outer containers. Therefore feature a_3 cannot support it either.

In such a set of container assemblies the outer containers will have identical outer dimensions, i.e. are the standardized outer containers adapted to be used with all kinds of analysis apparatuses. That it should be this standardised type is also indicated in by, paragraphs [0013] and [0020].

2.3.3 Features b_1 and b_2

While providing the assemblies known from D1 in a set with different inner container volumes the skilled person will have to maintain them compliant with semi-automated or automated testing equipment. The probes of such equipment, as discussed in point 2.1.2 above, have to find uniform conditions when entering the inner tube, i.e. a uniform upper part of the inner tube and a uniform level for the liquid specimen's upper surface. At the same time it is clear from D1 that the headspace should be as small as possible and should remain identical for all assemblies, to have consistency in its influence, see paragraph [0005], column 6, lines 2-10.

D1, teaches that the outer surface 52 of the upper part of the inner container 40 has to be in contact with the inner wall surface 20a of the outer standard size container 10a and that the inner surface 54 of this upper part is used for accommodating the container assembly's closure 60. Said closure will be chosen to be identical (feature b_1) for all assemblies in the set as it would be counter-productive to the idea of increasing the range of application of the assemblies of D1 to require at the same time different closures. As a result, the upper part of the inner containers will have to remain identical as well.

The inner container of D1, with its tapered connection between its upper part and the lower, sample containing, part enables, as discussed in point 2.1.2 above that the upper surface of the sample is at a standard level facilitating liquid retrieval and reducing the head space to a minimum. AS already argued this level is at the transition between the tapered part and the lower cylindrical part.

Taking account of the necessity to keep the volume of the headspace to a minimum, to inhibit evaporation as mentioned in D1, and the necessity to have the influence of this headspace consistent for the samples, the skilled person will obviously change only the dimensions, i.e. the storing capacity of the cylindrical lower part 42 of the inner container keeping at the same time its tapered part 58 and its upper cylindrical part 50 unchanged. The result will then automatically exhibit uniform head spaces for the different inner containers, claimed as feature b_2.

In fact, the skilled person is practically in a one-way-street situation, imposed by the requirements these assemblies have to fulfil as all evident term D1 and from the practical requirements in the field.

2.3.4 As stated in points 2.3.2 and 2.3.3 above, the Board finds that the individual inner containers 40 used in the set of container assemblies resulting from the skilled person's endeavours to solve the problems defined earlier will all have the same upper- and tapered part. To obtain the different volumes the skilled person has only three, equivalent, alternatives for the only remaining lower cylindrical part 42: namely by

changing only the wall thickness but, keeping the same height,

changing only the height but keeping the wall thickness unchanged,

or changing both the height and the wall thickness.

The present application proposes these three possibilities as being equivalent solutions, see page 9, lines 18 to 20 and figures 5 to 9. There is also no other indication in the present application concerning any specific technical advantages provided by changing only the wall thickness and keeping the height unchanged. As far as it concerns the appellant's argument that the person skilled in the art would have refrained from adapting only the wall thickness and keeping the height unchanged, the Board establishes that no evidence is given by the appellant for an existing prejudice against such a selection.

Selecting one out of these three equivalent, not-inventive possibilities therefore does not involve an inventive step.

2.3.5 For the above-mentioned reasons the subject-matter of claim 1 according to the auxiliary request 3 does not involve an inventive step and the requirements of Article 56 EPC are not met.

2.4 *Claim 1 of the main request and the auxiliary requests 1 and 2 - Inventive step, Article 56 EPC*

In accordance with the finding of point 1.5 above the subject-matter of claim 1 of the main request and the auxiliary requests 1 and 2 also does not involve an inventive step and the requirements of Article 56 EPC are not met.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:	The Chairman:
G. Nachtigall	H. Meinders