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Datasheet for the decision of 14 December 2021

Case Number: T 2228/16 - 3.2.02

Application Number: 07803367.7

Publication Number: 2073864

IPC: A61M1/36, A61M1/02

Language of the proceedings: EN

Title of invention:
Blood recuperation device and method

Patent Proprietor:
Gelanus B.V.

Opponent:
Brightwake Limited

Headword:

Relevant legal provisions:
EPC Art. 56, 83, 123(2)

Keyword:
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Amendments - extension beyond the content of the application as filed (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

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Case Number: T 2228/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 14 December 2021

Appellant: (Opponent)	Brightwake Limited Sidings Road Lowmoor Ind. Est. Kirby in Ashfield Nottingham, Nottinghamshire NG17 7JZ (GB)
Representative:	Adamson Jones BioCity Nottingham Pennyfoot Street Nottingham NG1 1GF (GB)
Respondent: (Patent Proprietor)	Gelanus B.V. Astraweg 1 8051 CJ Hattem (NL)
Representative:	De Vries & Metman Overschiestraat 180 1062 XK Amsterdam (NL)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 20 July 2016 concerning maintenance of the European Patent No. 2073864 in amended form.**

Composition of the Board:

Chairman	D. Ceccarelli
Members:	S. Böttcher
	C. Schmidt

Summary of Facts and Submissions

I. The opponent filed an appeal against the interlocutory decision of the Opposition Division to maintain European patent No. 2 073 864 on the basis of the third auxiliary request.

II. Oral proceedings before the Board were held by videoconference on 14 December 2021.

III. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed, i.e. that the patent be maintained as upheld in the contested decision (main request) or on the basis of the auxiliary request filed with the reply to the statement of grounds of appeal dated 18 April 2017.

IV. Claim 1 of the main request reads as follows:

"Blood filtering device (1) for the recuperation of blood from wound drained blood, in particular for an autologous blood transfusion system, comprising
an entrance port (3) for the blood, a first filter (7), a second filter (8), wherein the first filter (7) is arranged upstream of the second filter (8), the first filter (7) being adapted for removing emboli and/or large particulate matter from the blood received through the entrance port (3), and for allowing red blood cells to pass, the second filter (8) adapted for retaining red blood cells, and
an exit port (6) arranged between the first and second

filter (7,8), i.e. downstream of the first filter (7) and upstream of the second filter (8), characterised in that the second filter (8) has a pore size in the range of about 2-8 µm, the second filter (8) has an upstream surface which is substantially smooth at a micron size scale and has a main surface orientation at an angle to the horizontal in a range between 3 and 15 degrees, and the exit port (6) is located at least near the relatively lowest point or edge of the second filter (8)."

Claim 12 of the main request reads as follows:

"Autologous blood transfusion assembly comprising a blood filtering device (1) for the recuperation of blood from wound drained blood, in particular for an autologous blood transfusion system, comprising
an entrance port (3) for the blood,
a first filter (7) and
a second filter (8),
wherein the first filter (7) is arranged upstream of the second filter (8),
the first filter (7) being adapted for removing emboli and/or large particulate matter from the blood received through the entrance port (3) and for allowing red blood cells to pass,
the second filter (8) adapted for retaining red blood cells,
an exit port (6) arranged between the first and second filter (7,8), i.e. downstream of the first filter (7) and upstream of the second filter (8), wherein
the second filter (8) has a pore size in the range of about 2-8 µm, wherein the second filter (8) has an upstream surface which is substantially smooth at a micron size scale and has a main surface orientation at an angle to the horizontal in a range between 3 and 15

degrees and wherein the exit port (6) is located at least near the relatively lowest point or edge of the second filter (8)."

Claim 13 of the main request reads as follows:

"Method of recuperating a portion of blood from wound drained blood, in particular for an autologous blood transfusion, comprising the steps of
aspirating or collecting wound drained blood of a patient in a conduit,
filtering the blood from the conduit in a first relatively coarse manner with a first filter for removing emboli and/or particulate matter from the blood, filtering the coarsely filtered blood in a second relatively fine manner with a second filter for filtering out small impurities and/or liquid from the blood and retaining red blood cells in the residue, collecting the residue of the second filtering step, characterised in that
the second filter (8) has a pore size in the range of about 2-8 µm, wherein the second filter (8) has an upstream surface which is substantially smooth at a micron size scale and has a main surface orientation at an angle to the horizontal in a range between 3 and 15 degrees and wherein the exit port (6) is located at least near the relatively lowest point or edge of the second filter (8), and wherein the second filtering step is performed to retain particles having a size of more than about 2 µm and to remove smaller particles therefrom."

V. In the present decision, reference is made to the following documents:

D1: WO-A-2006/021728

D2: US-B-7,794,420
D4: US-A-4,898,572
D7: US-A-4,631,050
D8: US-A-5,722,964

VI. The arguments of the appellant can be summarised as follows:

Added subject-matter

Claims 1, 12 and 13 of the main request defined the second filter as having a main surface orientation at an angle of between 3 and 15 degrees. This range could not be derived directly and unambiguously from the original application. What were disclosed were the ranges 0 to 15 degrees and 0 to 6 degrees (claim 5 as originally filed) and the specific values 3 (claim 5 as originally filed, and page 9, lines 8 to 16 of the description as originally filed) and 6 (page 9, lines 8 to 16).

On page 9, lines 31 to 32 of the application as filed, the range of 3 to 15 degrees was disclosed only in combination with the filter being conical. The omission of the feature "conical" constituted an unallowable intermediate generalisation.

The wording "between 3 and 15" excluded the end point "3" from the claimed range.

Furthermore, the inclusion of the term "a portion of" in claim 13 contravened Article 123(2) EPC. It could not be derived from the application as filed that only a portion of the volume of the blood was recuperated. The term "a portion of" could not be considered to refer to a specific portion of blood (e.g. the red

blood cells). The claim language was broader and covered any portion of blood, e.g. a portion of the volume of blood from wound drained blood. Hence the claim wording constituted an unallowable intermediate generalisation.

Sufficiency of disclosure

The person skilled in the art would not be enabled to provide a filter having a pore size of 2 to 8 µm that was adapted to retain red blood cells, which have a size of about 4 µm (claims 1 and 12 of the main request), or to retain particles having a size of more than 2 µm (claim 13 of the main request).

Even if red blood cells might form chains or clumps of up to 10 µm, as mentioned in paragraph [0012] of the patent, claims 1 and 12 of the main request stated that the second filter was adapted for retaining single red blood cells rather than chains or clumps of these cells. Claim 13 of the main request did not refer to red blood cells at all, but only to particles.

The reference to other filtering mechanisms in paragraphs [0063] and [0068] was irrelevant, since the claims defined the second filter only in terms of its pore size.

The invention as defined in claims 1, 12 and 13 was not disclosed in a manner sufficiently clear and complete for it to be carried out across substantially the whole scope of the claims.

Inventive step

D1 was considered to represent the closest prior art

for the subject-matter of claims 1, 12 and 13 of the main request, and disclosed all the features of these claims, with the exception of the second filter having a main surface orientation at an angle to the horizontal in a range between 3 and 15 degrees.

A technical effect could not be recognised from this feature alone. Therefore the objective technical problem to be solved was simply the provision of an alternative filtration device.

The technical effect referred to in the decision could only be achieved by taking into account other factors, such as the viscosity of the blood, the flow velocity, the size of the filter, the pressure, and structural elements like the arrangement of baffles and valves. However, these factors were not mentioned in the claims.

In the embodiment of Figure 1 of D1, the membrane filter M of the filter 32 which was able to retain red blood cells was arranged substantially vertically. However, D1 did not provide any particular teaching regarding the orientation of the filter.

D7 disclosed an ultrafiltration unit comprising a semipermeable membrane which was oriented diagonally, but could also be oriented in any other suitable orientation (Figure 2, column 6, line 59 to column 7, line 5).

D8 disclosed a blood collection vessel comprising a filter barrier which was inclined at an angle of approximately 6 degrees, as depicted in Figures 1 and 1A.

Hence, in view of these teachings, the person skilled in the art would modify the device of D1 by orienting the filter 32 diagonally at an angle to the horizontal in the range of 3 to 15 degrees.

Furthermore, it was known from D4 to use slightly inclined filters in filtering systems (column 6, lines 3 to 11). The selection of the most appropriate filter orientation was a matter of routine optimisation and did not require any inventive skill.

Consequently, the subject-matter of claims 1, 12 and 13 lacked an inventive step over D1 in combination with D7 or D8, or with the common general knowledge as exemplified by D4.

VII. The arguments of the respondent can be summarised as follows:

Added subject-matter

The disclosure on page 9, lines 9 to 16 taught that a range between 3 and 6 degrees was preferred. Furthermore, the range of 3 to 15 degrees was disclosed for embodiments comprising concave, conical or spherical filters.

It could be derived from the passage on page 9, lines 14 to 16 that an angle of 3 degrees was included in the claimed range.

Furthermore, it could be derived directly and unambiguously from the application as filed that an intermediate-sized portion of the blood was retained in the residue of the second filtering step, and that the portion of the blood in the residue was recuperated.

This was also disclosed in the application as filed on page 1, line 14 to page 2, line 2; page 3, lines 24 to 32; page 4, lines 19 to 29; page 5, lines 8 to 15; and page 14, lines 21 to 27.

Consequently, claims 1, 12 and 13 of the main request did not include added subject-matter.

Sufficiency of disclosure

The natural occurrence of red blood cells was in the form of small chains or clumps of up to about 10 µm. Such chains or clumps could be retained by a second filter as defined in claims 1, 12 or 13 of the main request.

Furthermore, paragraph [0016] of the patent taught that the disadvantages of a relatively coarse second filtering step were outweighed by the additional reduction of larger impurities and the improved handling of the device.

The additional filter mechanisms mentioned in paragraphs [0063] and [0068] were not essential to the functioning of the blood filtering device *per se*.

The claimed subject-matter was therefore sufficiently disclosed.

Inventive step

D1 disclosed that the membrane M of the filter 32 had a pore size of 0.5 to 5 µm. After large particles and bone fractions had been removed from the haemorrhage fluids by filter 26, this filter was used to concentrate the red blood cells by removing fluid while

leaving in as many small particles as possible.

The separation/concentration filter 32 of D1 and its membrane M were oriented essentially vertically. Hence D1 did not disclose that the filter had a main surface orientation at an angle to the horizontal in a range between 3 and 15 degrees. Rather, it was essential for the filter of D1 to be kept upright in order to be able to fill it with fluid up to the outlet 38 (page 6, lines 3 to 6).

An angle of 3 to 15 degrees as defined in claims 1, 12 and 13 of the main request provided effective filtering of fluids and small impurities, while guiding the red blood cells to an exit port (paragraphs [0040] and [0042] of the patent).

Hence the technical problem of the patent was to remove specific smaller fractions from the blood.

D7 disclosed an ultrafiltration unit having a semipermeable membrane adapted to retain red blood cells but also small particles. While it was mentioned in D7 that the membrane was arranged diagonally, the claimed orientation at an angle to the horizontal in the range of 3 to 15 degrees was not disclosed. Hence, if the person skilled in the art had considered a combination of D1 and D7, this combination would not have resulted in a device according to claim 1, an assembly according to claim 12 or a method according to claim 13 of the main request.

D8 related to a blood collection device 10 comprising a filter FL to catch larger particulate material and macroemboli, so that blood which seeped through the mesh and reached the outlet 6 below the filter was

suitable for reinfusion (Figure 1; column 3, lines 42 to 48; column 6, lines 49 to 52). Hence the filter FL could be regarded as the first filter as claimed in the patent. However, D8 did not disclose a second filter for filtering out small impurities and retaining the red blood cells. In fact, D8 did not mention red blood cells at all. Thus, although the filter mesh of D8 was slightly inclined, D8 was not instructive for orienting the second filter as claimed.

D4 also lacked a second filter for retaining red blood cells and the associated filtering step. The fact that conical filters were known at the priority date did not render the subject-matter of the claims obvious.

Consequently, neither D1 alone nor D1 in combination with D7 or D8 suggested the claimed features of the second filter. The subject-matter of claims 1, 12 and 13 was therefore based on an inventive step.

Reasons for the Decision

1. *Subject-matter of the invention*

The invention relates to a blood filtering device and a method for the recuperation of blood from fluid drained from a wound. The aim is to filter out blood which is as rich as possible in healthy red blood cells of the drained blood. The recuperated blood, which should be free of contaminants, can then be re-infused into the patient. Hence large impurities, such as tissue and bone fragments and blood clots, have to be removed, as well as small particles (smaller than the red blood

cells) such as platelets, plasma proteins and antibodies (paragraphs [0002] to [0006] of the patent).

According to claim 1, the filtering device (Figure 1) has an entrance port 3, a first filter 7 and a second filter 8. An exit port 6 is arranged between the filters. The first filter 7 is adapted for removing emboli and/or large particulate matter from the blood, and for allowing red blood cells to pass. The second filter 8 is adapted for retaining red blood cells and has a pore size in the range of about 2 to 8 µm. Its upstream surface is substantially smooth at a micron size scale and has a main surface orientation at an angle to the horizontal in a range between 3 and 15 degrees. The exit port 6 is located at least near the relatively lowest point or edge of the second filter.

Claim 12 relates to an autologous blood transfusion assembly comprising a blood filtering device as defined in claim 1.

Claim 13 relates to a method of recuperating a portion of blood from wound drained blood, comprising the steps of aspirating or collecting wound drained blood in a conduit, filtering the blood in a first relatively coarse manner with a first filter, filtering the coarsely filtered blood in a second relatively fine manner with a second filter for filtering out small impurities and/or liquid and retaining red blood cells in the residue, and collecting the residue of the second filtering step. The second filter has the same structural properties as the filter of claim 1, and an exit port is located near the lowest point of the second filter. It is further specified in claim 13 that the second filtering step is performed to retain particles having a size of more than about 2 µm and to

remove smaller particles.

2. *Main request - added subject-matter*

2.1 Main surface orientation at an angle in a range between 3 and 15 degrees

The application as filed mentions that an angle of more than 15 degrees provides insufficient filtration, while an angle of 3 degrees provides effective filtering of impurities and fluids (page 9, lines 9 to 16). The person skilled in the art is further taught by the application as filed (page 8, lines 31 to 35) that the angle of the filter with respect to the horizontal determines the flow velocity of the blood towards the exit port, i.e. the smaller the angle, the longer the filtration time. Hence it can be derived that a range of 3 to 15 degrees provides the optimum results in view of both filtration time and effectiveness.

Furthermore, the range of 3 to 15 degrees is mentioned on page 9, lines 31 to 34 in connection with a concave or conical filter. The Board holds that the specific shape of the filter is not inextricably linked to the claimed range of angles. The appellant did not explain why this should be the case.

The wording "between 3 and 15" in claims 1, 12 and 13 is considered to include the extremes. Hence an angle of 3 degrees is included in the range. This is consistent with the application as filed, which mentions "about 3 degrees" (page 9, lines 14 to 16) and "about 3-15 degrees" (page 9, lines 31 to 34).

Hence the claimed range of between 3 and 15 degrees for the angle of the filter orientation can be derived

directly and unambiguously from the original application.

2.2 Recuperating a portion of blood

Claim 13 as originally filed includes the steps "filtering the (...) blood in a second relatively fine manner (...) and retaining red blood cells in the residue" and "collecting the residue of the second filtering step". The same steps are included in claim 13 of the main request. It can be derived directly and unambiguously from this wording that only a portion of the blood drained from a wound is recuperated, namely the residue of the second filter containing the red blood cells. Furthermore, the feature concerning the recuperation of a portion of blood within the meaning of claim 13 is based on several passages of the description as filed, i.e. page 1, line 14 to page 2, line 2; page 3, lines 24 to 32; page 4, lines 19 to 29; page 5, lines 8 to 15; and page 14, lines 21 to 27. Hence the inclusion of the term "a portion of" in claim 13 does not involve added subject-matter.

2.3 It follows that claims 1, 12 and 13 do not contravene Article 123(2) EPC.

3. *Main request - sufficiency of disclosure*

Sufficiency of disclosure has to be considered in view of the teaching of the patent as a whole.

According to the patent (paragraph [0012]), red blood cells can be retained even by a filter having a pore size of about 8 µm since they naturally form small chains or clumps about 10 µm in size. This was not contested. The Board notes that the wording of claims

1, 12 or 13 requires neither that single red blood cells be retained nor that all the red blood cells present in the fluid be retained.

As regards claim 13, which specifies that the second filtering step is performed to retain particles having a size of more than about 2 µm, the patent teaches that the smoothness and the surface orientation of the filter as claimed contribute to the retention capabilities of the filter (paragraph [0040]). By adjusting these parameters together with the pore size of the second filter within the claimed limits, the person skilled in the art can obtain the claimed retention of particles having a size of more than about 2 µm. Moreover, the patent teaches additional parameters (paragraphs [0063] and [0068]) which may have an effect on the filter properties. The person skilled in the art could also consider this teaching in order to carry out the invention as defined in claims 1, 12 and 13.

Hence the invention as defined in claims 1, 12 and 13 is sufficiently disclosed for it to be carried out by the person skilled in the art, in compliance with Article 83 EPC.

4. *Main request - inventive step*

4.1 D1 relates to a blood recuperation device comprising the features of the preamble of claim 1 (Figure 1). The filter 26 can be considered the first filter, and the separation/concentration filter 32 can be considered the second filter (page 5, lines 14 to 24). This second filter is a flexible pouch that is divided by a membrane M into two volumes, V1 and V2 (page 5, line 25 to page 6, line 6, Figure 2). The red blood cells are

retained in volume V1. The flexible pouch has an exit port 36 in its lower part, which is connected to volume V1. Figures 1 and 2 show that the second filter is arranged vertically, i.e. has a surface orientation at an angle to the horizontal of 90 degrees.

It is common ground that D1 does not disclose that the second filter has a main surface orientation at an angle to the horizontal in a range between 3 and 15 degrees.

4.2 In conjunction with the smoothness of the filter surface and the pore size, the claimed angle contributes to the effective removal of small impurities within a reasonable filtration time, while reducing the risk of damaging the red blood cells (paragraphs [0040] and [0042] of the patent).

Hence the objective technical problem to be solved by the present invention is to enhance the quality of the recuperated blood.

4.3 The orientation of the second filter as defined in claims 1, 12 and 13 of the main request is not rendered obvious by any of D7, D8 and the common general knowledge of the person skilled in the art, as exemplified by D4.

D1 does not teach the provision of the second filter at an angle as claimed.

The Board does not agree with the appellant that the selection of the filter orientation was a matter of routine activities performed by the person skilled in the art. As explained, the selection of a filter orientation as claimed addresses a specific problem. It

would have required substantial modification of the device disclosed in D1, which the person skilled in the art would not have done without an express pointer in that direction. In this regard, it is irrelevant that conical, inclined filters were known from D4 at the priority date.

Moreover, the teaching of D7 or D8 does not motivate the person skilled in the art to modify the filter arrangement of D1.

D7 relates to an autotransfusion system for salvaging, washing and concentrating blood from an operative field of a patient. The blood is filtered in a filtration unit 20 and then conveyed to an ultrafiltration unit where a portion of the fluid is removed (abstract). In the embodiment of Figure 2, the membrane 60 of the ultrafiltration unit, which serves to retain blood cells, is arranged diagonally. It is mentioned in column 7, lines 2 to 5 that the membrane could be oriented "in any other suitable orientation".

However, D7 does not address the problem of enhancing the quality of the recuperated blood, and does not suggest arranging the filter membrane at an angle of between 3 and 15 degrees to the horizontal. Thus a combination of the teaching of D7 with the device of D1 does not render the subject-matter of claims 1, 12 or 13 of the main request obvious.

D8 relates to a blood collection vessel comprising a filter located in the blood path between the inlet and the outlet of the vessel. The filter is arranged to keep clots away from the outlet but suspended in the collected blood. In the embodiment of Figure 1, the floor of the vessel is slightly inclined, and the

filter is arranged parallel to the floor. The device of D8 does not include any second filter as defined in claims 1 and 13 for removing fluid and small particles. Hence D8 does not address the quality of the filtered blood and cannot prompt the person skilled in the art to arrange the second filter of the device of D1 in the claimed manner.

4.4 It follows that the subject-matter of claims 1, 12 and 13 involves an inventive step (Article 56 EPC).

4.5 In conclusion, none of the appellant's objections prejudice maintenance of the patent on the basis of the main request.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe D. Ceccarelli

Decision electronically authenticated