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### Datasheet for the decision of 27 June 2008

T 0690/05 - 3.3.05 Case Number:

Application Number: 02078995.4

Publication Number: 1275410

B01D 29/01 IPC:

Language of the proceedings: EN

Title of invention:

A filter device for removing leukocytes

Applicant:

Fenwal, Inc.

Opponent:

Headword:

Filter device/FENWAL

Relevant legal provisions:

EPC Art. 76(1)

Relevant legal provisions (EPC 1973):

### Keyword:

"Extension beyond the content of the earlier application as filed (all requests)"

### Decisions cited:

T 0066/85, T 0331/87

#### Catchword:



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Boards of Appeal

Chambres de recours

Case Number: T 0690/05 - 3.3.05

DECISION
of the Technical Board of Appeal 3.3.05
of 27 June 2008

Appellant: Fenwal, Inc.

Three Corporate Drive

Lake Zurich IL 60047 (US)

Representative: Geary, Stephen

Bawden & Associates 4 The Gatehouse 2 High Street Harpenden

Herts AL5 2TH (GB)

Decision under appeal: Decision of the Examining Division of the

European Patent Office posted 18 January 2005 refusing European application No. 02078995.4

pursuant to Article 97(1) EPC 1973.

Composition of the Board:

Chairman: G. Raths

Members: J.-M. Schwaller

S. Hoffmann

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## Summary of Facts and Submissions

- I. This appeal lies from the decision of the examining division to refuse European patent application

  No. 02 078 995.4. The decision was based on the set of claims filed on 23 November 2004 which according to the examining division did not meet the requirements of Article 76(1) EPC.
- II. With the grounds of appeal dated 25 May 2005, the appellant filed two sets of amended claims as a main request and a first auxiliary request, respectively.

Claim 1 of the 1<sup>st</sup> auxiliary request reads as follows:

"1. A blood filter device for removing leukocytes from whole blood or red blood cells comprising a filter housing (18) enclosing a filter pad assembly (20), the filter pad assembly comprising multiple fibrous layers (40) for removing leukocytes, the housing (18) comprising a first flexible housing sheet (44) at an inlet side of the filter pad assembly and a second flexible housing sheet (46) at an outlet side of the filter pad assembly, wherein

the layers of the filter pad assembly have their peripheries bonded together and bonded with the peripheries of the housing sheets by a peripheral heat and pressure seal (48) that encapsulates the filter pad assembly between the housing sheets, and including an inlet port (36) in the first housing sheet that is spaced from the peripheral seal and in fluid communication with the inlet side of the filter pad assembly, and an outlet port (38) in the second housing sheet that is spaced from the peripheral seal and in

fluid communication with the outlet side of the filter pad assembly."

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- III. In a communication dated 31 January 2008, the board expressed its provisional opinion that the subject-matter of claim 1 of these two requests did not appear to have a basis in the parent application in its version published as WO 95/17234 (hereinafter called "earlier application").
- IV. In response to the summons to oral proceedings, the appellant submitted on 26 June 2008 three sets of claims as a new main request and first and second auxiliary requests. It also withdrew the previous main request and made the 1<sup>st</sup> auxiliary request submitted on 25 May 2005 its 3<sup>rd</sup> auxiliary request.

Claim 1 of the main request reads:

"1. A filter device (16) for removing leukocytes from blood or blood components containing leukocytes which comprises a filter housing (18) comprising a first flexible housing sheet (44) and a second flexible housing sheet (46), an inlet port (36), an outlet port (38), the filter housing (18) enclosing a filter pad assembly (20) to remove leukocytes and to otherwise allow flow of the blood or blood components through the device (16)."

Claim 1 of the 1<sup>st</sup> auxiliary request reads:

"1. A filter device (16) for removing leukocytes from blood or blood components containing leukocytes which comprises a filter housing (18) comprising a first flexible housing sheet (44), a second flexible housing sheet (46), an inlet port (36) an outlet port (38), the filter housing (18) enclosing a leukocyte filter pad assembly (20) to remove leukocytes and to maintain flow of the whole blood or blood components passing through the device (16), said filter pad assembly comprising a first media region comprising multiple layers of a fiber mat and a second media region comprising a stacked fiber media."

Claim 1 of the 2<sup>nd</sup> auxiliary request reads:

- "1. A filter device (16) for removing leukocytes from blood or blood components containing leukocytes which comprises a leukocyte filter housing (18) comprising a first flexible sheet (44) having an inlet port (36) for conveying the blood or blood components to the filter device (16) and a second flexible housing sheet (46) having an outlet port (38) for conveying leukocyte depleted blood or blood components from the filter device (16), the filter housing (18) enclosing a filter media (20) adapted to remove the leukocytes and to maintain flow of the blood or blood components through the device (16)."
- V. Oral proceedings took place on 27 June 2008.
- VI. The appellant argued that there was a basis for the subject-matter presently claimed at page 1, lines 3 to 8; page 7, lines 19, 23; page 9, lines 23 to 29; page 10, lines 18 to 25; page 11, lines 7 to 13; page 17, line 30 to page 18, line 21; Figures 2, 6 and 7 of the earlier application.

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It further cited the decisions T 66/85 and T 331/87 in support of its argumentation.

VII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the examining division with the order to grant a patent on the basis of the claims according to the main request or to the 1<sup>st</sup> or 2<sup>nd</sup> auxiliary request, all three requests filed on 26 June 2008, or in the alternative on the basis of the claims according to the 3<sup>rd</sup> auxiliary request filed as first auxiliary request on 25 May 2005.

### Reasons for the Decision

- 1. Concerning the allowability under Article 76(1) EPC of amended claim 1 main request
- 1.1 The present application is a divisional application of earlier European application No. 95906087.2 published as WO 95/17234. This earlier application had four claims, which were all directed to a method for determining the average fiber diameter of a filtration media.
- 1.2 In contrast, the claims of the present application are directed to a **filter** device and a method of manufacturing said device.

Claim 1 of the main request includes the following structural features:

- A housing (18) comprising:
  - a first flexible housing sheet (44),

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- a second flexible housing sheet (46),
- an inlet port (36),
- an outlet port (38).
- A filter pad assembly (20) enclosed in the filter housing.

None of these features have a counterpart in the claims of the earlier application.

The counterpart for the expressions "filter device", "for removing leukocytes", also recited in present claim 1 is also missing in the claims of the earlier application.

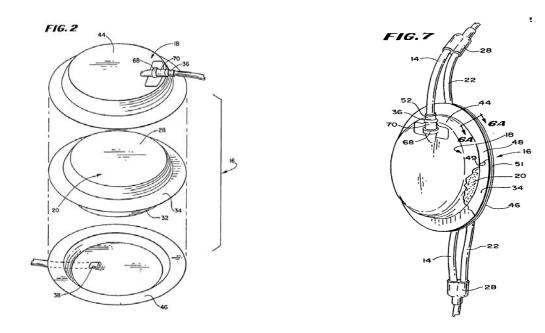
- In fact, the sole disclosure in the earlier application relating to a device for filtering leukocytes can be found in the description specifically at pages 7 to 21 thereof under the heading "Description of the preferred Embodiments", wherein a blood collection assembly 10 for filtering leukocytes from red blood cells before transfusion is depicted. Specific sections of the assembly 10 are detailed under the subheadings "The Filtration Device" (pages 9 to 12), "The First Media Region" (pages 12 to 13), "The Second Media Region" (pages 13 to 15), "The Third Media Region" (pages 15 to 17), "The Filter Housing" (pages 17 to 21), respectively.
- 1.4 The combination of features recited in present claim 1 is however neither literally disclosed in the earlier application, nor is it directly and unambiguously derivable therefrom. The passages and Figures indicated by the appellant (see item VI.) in support of a counterpart are defective for the following reasons:

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- 1.4.1 The passage at page 1, lines 3 to 8, which reads:

  "Field of the Invention: The invention generally relates to blood collection and processing systems and methods. In a more particular sense, the invention relates to systems and methods for removing leukocytes from red blood cells before transfusion or long term storage" only describes in broad terms the alleged invention, without however specifying anyone of the structural features (18) (44), (46), (36), (38) and (20) presently claimed.
- 1.4.2 The passage at page 7, lines 19 to 23, which reads "As Figs. 2 and 7 best show, the filter device 16 includes a two part housing 18 that encapsulates a filter pad assembly 20. The pad assembly 20 is intended to be used to remove leukocytes from red blood cells.", calls for a similar remark, as not all the structural features of present claim 1 are disclosed therein.
- 1.4.3 Concerning the Figures 2 and 7 cited in the above passage, as can be seen from the reproductions thereof hereinafter, the devices illustrated therein encompass not only the features (18), (44), (46), (36), (38) and (20) defined in present claim 1, but also <u>further</u> structural features, for instance those identified with the reference numbers (68), (70) or (34), which are however missing in claim 1 under consideration.

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1.4.4 The next passage (page 9, lines 23 to 34) quoted by the appellant, which also makes reference to the above Figures 2 and 7, reads: "The filter device 16 can be variously constructed. In the illustrated and preferred embodiment (best shown in Figs. 2 and 7), the outer housing 18 enclosing the filter pad assembly 20 comprises two sheets 44 and 46 of flexible plastic material. The housing 18 is thus "soft", instead of rigid. Also in the illustrated and preferred embodiment, the filter device 16 includes tangential side ports, one port 36 (in sheet 44) serving as an inlet and the other port 38 (in sheet 46) serving as an outlet."

As indicated in its first lines, this passage concerns a preferred embodiment, but again, not only the structural features of the filter device of present claim 1 are disclosed therein, but also the further following non-optional features:

- the flexible material of the sheets 44 and 46 is plastic
- the ports 36 and 38 are tangential side ports

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- the ports are <u>located in sheets 44 and 46</u>, respectively.

The board furthermore observes that the enumeration of the structural features constituting this preferred embodiment goes on in the next paragraph with a passage - not quoted by the appellant as a basis for present claim 1 - which discloses *inter alia* that "the ports 36 and 38 are arranged about 180 degrees apart on opposite flow sides of the filter device 16 (see Figs. 1 and 2)".

In view of the above findings that the "illustrated and preferred embodiment (best shown in Figs. 2 and 7)" described at page 9, lines 25 ff. encompasses non-optional features which have been arbitrarily omitted from the combination of features presently recited in claim 1, the subject-matter of present claim 1 cannot be considered as deriving directly and unambiguously from the passage or Figures mentioned hereinabove.

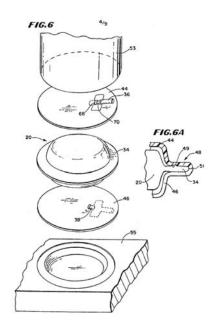
1.4.5 The passage at page 17, line 30 to page 18, line 21 reads: "As Fig. 6 show, the filter device housing 18 comprises two sheets 44 and 46 of flexible, inert, thermoplastic material. For example, plasticized medical grade polyvinyl chloride material can be used. The sheets 44 and 46 are fused about their periphery by the application of heat and pressure against opposite sides of the peripheral seal 34 of the filter pad assembly 20. The sheet 44 overlies the first media region 28 of the filter pad assembly 20. The sheet 46 overlies the third media region 32 of the filter pad assembly 20. As Fig. 6A best shows, the fused perimeters of the sheets 44 and 46 form an integrated or composite seal 48. The inner portion 49 of the seal

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48 integrally bonds the material of the sheets 44/46 with the peripheral seal 34 of the filter pad assembly 20. The outer portion 51 of the seal 48 bonds the material of the sheets 44/46 together. The exterior of the sheets 44 and 46 conform about the symmetrical shape of the enclosed filter pad assembly 20. The integrated seal 48 encapsulates the filter pad assembly 20 between the housing sheets 44/46 in a straightforward, one step process."

The underlined features (underlining added by the board) in the above passage are neither recited in present claim 1 nor described as optional.

It can moreover be seen from the Figures 6 and 6A reproduced hereinafter that the device illustrated therein encompasses not only the features (18), (44), (46), (36), (38) and (20) defined in present claim 1, but also other structural features which are missing in present claim 1.



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In view of these findings, the same reasons as those indicated in item 1.4.4 apply, and therefore the subject-matter of claim 1 can also not be considered as being directly and unambiguously derivable from the above passage or Figures.

1.4.6 The appellant further quoted the passages at page 10, lines 18 to 34 and page 11, lines 7 to 13, which disclose the advantages of a flexible filter housing over rigid housings. It cited in this respect the decisions T 331/87 and T 66/85 and argued in view of the outcome thereof that the skilled person would immediately recognize that claim 1 included the minimal essential components required for removing leukocytes and overcoming the technical problems associated with rigid filtration devices.

The board does not accept this argumentation because the above decisions are not applicable to the present case as they concern the deletion of a non-essential feature from an existing claim, which situation is quite different from the present one, in which the essential structural features recited in present claim 1 have no basis at all in the claims of the earlier application.

As the above decisions are not applicable to the present, the further argument that the skilled person would immediately recognize that claim 1 included the minimal essential components required for solving the above problems becomes irrelevant.

1.5 For the above reasons, the subject-matter of claim 1 according to the main request extends beyond the

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content of the earlier application as filed and the requirements of Article 76(1) EPC are thus not fulfilled.

2. Concerning the allowability under Article 76(1) EPC of amended claim  $1 - 1^{st}$  to  $3^{rd}$  auxiliary requests.

None of the claims 1 of these three requests recite all the features that the board identified hereinabove as non-optional in the specific embodiments illustrated in the passages and/or Figures of the earlier application quoted by the appellant (see item VI.).

As the board also did not find a basis for these claims elsewhere in the earlier application, the reasons given above for the main request apply mutatis mutandis to the present requests, which therefore also contravene Article 76(1) EPC.

### Order

### For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

S. Fabiani

G. Raths