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D E C I S I O N
of 17 July 2003

Case Number: T 0780/01 - 3.3.5

Application Number: 95906089.8

Publication Number: 0684867

IPC: B01D 25/00

Language of the proceedings: EN

Title of invention:

Blood filter and method of its manufacturing

Patentee:

BAXTER INTERNATIONAL INC.

Opponent:

Maco Pharma

Headword:

-

Relevant legal provisions:

EPC Art. 56, 111(1), 114(1)

EPC R. 29(1), 57(a), 67

Keyword:

"Inventive step (yes) - exclusion of hindsight"

Decisions cited:

-

Catchword:

-



Case Number: T 0780/01 - 3.3.5

D E C I S I O N
of the Technical Board of Appeal 3.3.5
of 17 July 2003

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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 15 May 2001
rejecting the opposition filed against European
patent No. 0684867 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: R. K. Spangenberg
Members: A. T. Liu
J. H. Van Moer

Summary of Facts and Submissions

I. European patent No. 0 684 867 was granted with a set of 12 claims, of which claim 1 was directed to a blood filter device with claims 2 to 7 depending thereon and claim 8 directed to a method for manufacturing a filter device according to claim 1, with claims 9 to 12 depending thereon.

II. Claim 1 read as follows:

"A blood filter device comprising a filter housing (18) enclosing a filter pad assembly (20), the filter pad assembly comprising first, second and third layers (28,30,32), the housing (18) comprising a first flexible housing element (44) overlying the first layer (28) and a second flexible housing element (46) overlying the third layer (32), the periphery of the filter assembly (20) and a rim of each housing element (44,46) being integrally bonded by a heat and pressure seal (48), whereby the filter assembly (20) is encapsulated in the housing, an inlet port (36) in the first housing element (44) for conveying blood to the filter (20) and an outlet port (38) in the second housing element (46) for conveying blood from the filter (20), characterised in that each filter layer (28,30,32) comprises a filter medium with the three layers having their peripheries bonded together and bonded with the rims of the housing elements (44,46) in said heat and pressure seal, the first housing element (44) overlying the first layer (28) and the second housing element (46) overlying the third layer (32), which is made of a woven, or knitted material, to interrupt occluding

surface contact of the collapsible second filter housing element (46) with the filter assembly (20) during drainage."

III. An opposition was lodged against the patent on the grounds of Article 100(a), (b) and (c) EPC and supported, *inter alia*, by the following document:

D1: EP-A-0 526 678

IV. The appeal was from a decision of the Opposition Division rejecting the opposition. It was held that the prior art did not give the skilled person any incentive for modifying the arrangement of the inlet and outlet ports of D1 such as to have these ports mounted within the housing elements.

V. With the statement of the grounds of appeal, the appellant made reference for the first time, *inter alia*, to the following document:

D10: EP-A-0 516 846

The appellant also set out the arguments to show that the subject-matter of claim 1 lacked an inventive step in view of the prior art.

VI. By letter of 3 May 2002, the respondent noted that the ground of opposition under Article 100(b) and (c) EPC was not contained in the appeal. In addition, arguments were submitted to show that the claimed blood filter device was inventive over D1, either taken alone or in combination with any of the other cited documents.

VII. At the oral proceedings on 17 July 2003, the respondent filed a set of amended claims as basis for an auxiliary request.

VIII. The appellant's arguments may be summarised as follows:

- The subject-matter of claim 1 was distinguished from the closest prior art according to D1 by three technical features. These distinguishing features solved different technical problems and therefore had to be examined independently using the problem/solution approach.
- The modification of the filter as proposed in claim 1 was obvious in view of D1 in combination with the disclosure of D10.

IX. The respondent's arguments were essentially the following:

- The overall problem to be solved was to provide an improved blood filter device. All the distinguishing features must be considered collectively when assessing inventive step since they all contributed to improving the performance of the device.
- The patent in suit also addressed the problem of fluid bypassing the filter and that of downstream occlusion of the filter pad. These problems were solved in a manner that simplified the construction of the filter device.

- In D1, the filter pad was bonded to the housing via a pliable frame. There was no teaching or suggestion in D1 that would lead the skilled person to dispense with that pliable frame and instead have the filter pad assembly integrally bonded to the outer housing.
 - There was no reason for the skilled person to choose to position the ports as in claim 1 from the various options as offered in D10.
- X. The appellant requested that the decision under appeal be set aside and that the patent be revoked. Auxiliarily, it was requested that the case be remitted to the department of the first instance and the appeal fee be reimbursed.
- XI. The respondent requested that the appeal be dismissed and the patent be maintained as granted or, in the alternative, on the basis of the auxiliary request filed at the oral proceedings.

Reasons for the Decision

Main request

1. *Grounds of opposition under Article 100(b) and (c) EPC*

As is correctly observed by the respondent, the findings of the opposition division on the question of lack of disclosure and added subject-matter were not challenged by the appellant at the appeal proceedings (see Reasons for the decision, items 2 and 3 and the

respondent's letter dated 3 May 2002, items 4 and 5). Nor can the Board recognise any need for re-examining the facts of its own motion (Article 114(1) EPC).

2. *Ground of opposition under Article 100(a) EPC*

2.1 Novelty

It is undisputed that the device according to claim 1 is new. This will also be clear from the following discussion on inventive step.

2.2 Inventive step

2.2.1 Claim 1 is directed to a blood filter device comprising a filter housing enclosing a filter pad assembly.

2.2.2 It is common ground that the closest prior art is represented by D1 which is also directed to a blood filtration device. D1 discloses a filter bag comprising an envelope (or filter housing) formed by sealing the periphery (25) of two plastic sheets (9, 10). A filter pad (11) is maintained in place within a pliable frame (12) which is used to delimit two separate compartments (13, 14) within the filter housing. These compartments are in fluid communication with the exterior through flexible in- and outlet tubes (15, 16) which are sandwiched between the flexible sheets constituting the filter housing. The pliable frame consists of two plastic sheets (17, 18) sealed together at the periphery (19) of the filter pad and on the periphery (25) of the filter housing (see column 4, line 3 to column 5, line 13 and Figures 2 to 4). In addition, the filter device also incorporates flexible rods (21, 22)

at the interior of the plastic sheet (10) on its downstream side. These are sealed onto the periphery (25) of the filter bag (column 5, lines 22 to 40 and Figure 5).

2.2.3 The respondent at first asserted that the problem that the patent in suit set out to solve was to improve the filter device according to D1. As has later arisen from the discussion at the oral proceedings, however, the respondent has not argued that the device as claimed works better than the known device according to D1. In fact, the gist of the patent in suit is to address two distinct key aspects and the solution proposed here is to simplify the construction of the filtration device. The Board therefore can see the technical problem with respect to D1 in the provision of a further blood filtering device which solves the following partial problems in a manner that simplifies its construction:

- (a) the problem of preventing fluid bypassing a multi-layer pad assembly positioned in a flexible housing and
- (b) the problem of preventing downstream occlusion of the filter pad assembly by the flexible housing when the filter is in use.

This view is also consistent with the respondent's written submissions (see the respondent's letter dated 3 May 2002, page 4, second full paragraph).

2.2.4 In order to solve the above indicated technical problems, it is stipulated in claim 1 that:

(i) the inlet and outlet ports for conveying blood to and from the filter be positioned in the upstream and downstream housing elements making up the filter housing,

(ii) the three-layer pad assembly be encapsulated in the flexible filter housing, with these filter layers having their peripheries integrally bonded together and bonded with the rims of the housing elements.

(iii) the third filter layer be made of a woven or knitted material.

2.2.5 By choosing the third filter layer to be made of a woven or knitted material and by arranging the inlet and outlet ports to be within the plastic housing sheets instead of being sandwiched between these sheets, all the layers of the filter pad assembly can be peripherally bonded to one another and integrally bonded with the rims of the flexible housing elements. To the Board, it is plausible that the integral bonding between the filter pad assembly and the flexible housing elements, which solves the partial problem of fluid bypass, would be made more difficult if the ports were sandwiched between these housing elements. It is indeed uncontested that the construction of the filter device as claimed is simplified with respect to the prior art. It is also common ground that the third filter layer further solves the partial problem of preventing downstream occlusion of the filter pad assembly when the filter is in use.

In consequence, it is manifest that the technical problem(s) as stated in point 2.2.3 above is/are indeed solved by the claimed device. The only question left to be elaborated upon is whether the solution as proposed in claim 1 is obvious in view of the available prior art.

2.2.6 Re: distinguishing feature (i)

Positioning of the inlet and outlet ports.

The appellant has contended that the device as proposed in claim 1 is obvious in view of D1 in combination with D10 which, being directed to a filter suitable for medical final filtering or blood transfusion, is in the same technical field as D1 and the patent in suit (column 1, lines 1 to 8). The filter according to D10 is produced by heat sealing heat-fusible films to a filter membrane, thereby forming a closed baggy space on both sides of the filter membrane. Each of these baggy spaces is provided with an inlet from or outlet to a circuit (column 2, lines 1 to 24). In this respect, D10 expressly discloses various possibilities for arranging these inlet and outlet ports. In one embodiment, the inlet and outlet ports are in the housing films and fused to these films to prevent fluid leakage (column 2, line 45 to column 3, line 4 and Figures 1 to 3). As a further option, the inlet and outlet tubes can also be fused between the housing films and the filter membrane at their edges (column 4, lines 7 to 13 and Figures 8 and 9). The appellant has then concluded that it is a matter of choice, depending on the circumstances and not on inventive activity, to

position the ports in the housing elements as in claim 1 or between these elements as in D1.

As is correctly noted by the respondent, however, in both embodiments cited by the appellant, either according to Figures 1 to 3 or to Figures 8 and 9 of D10, the filter device comprises a single filter membrane that is sandwiched between two flexible housing elements. In the case where the filter device comprises more than one filter membrane, the inlet and outlet ports are sandwiched between the housing elements (column 5, lines 26 to 45 and Figure 14). In the Board's judgment, D10 therefore does not clearly and unambiguously offer the choice of arranging the inlet and outlet ports in the filter housing when the filter device incorporates a multi-layer filter pad, as is the case for D1 and the patent in suit.

2.2.7 Re: distinguishing feature (ii)

Integral bonding of the filter pad and the housing elements.

The appellant has remarked that fluid bypassing and leaking is also prevented in D10 by fusing the plastic films forming the filter housing to the filter membrane (see D10, column 2, lines 1 to 24). Since claim 1 proposes the same solution to the same technical problem, the integral bonding as stipulated in claim 1 is obvious in view of this prior art teaching.

The Board notes that it is explicitly indicated in D1 that the problem of leaking (or fluid bypassing) is resolved at two levels (see in particular column 4, lines 20 to 33):

- (a) first, by a string (19) of peripheral seal fixing the filter pad (11) to the centre of the pliable frame (12) and
- (b) second, by another peripheral seal bonding the periphery of the pliable frame (12) to the plastic sheets (9,10) forming the housing elements, and the inlet and outlet tubes (15,16).

It is therefore undisputable that the pliable frame is an essential element of the device of D1 and that there is no disclosure or suggestion in D1 to dispense with that frame. In the Board's judgment, when seeking an alternative to the device of D1 with the aim to make its construction simpler, the skilled person a priori does not get any incentive from D1 to have the filter pad assembly integrally bonded directly to the filter housing instead of it being bonded via a pliable frame.

2.2.8 Re: Combination of distinguishing features (i) and (ii)

The appellant has alleged that, when assessing inventive step, the development of the present modification must be seen in the correct context. Historically, the earlier commercially available blood filters are all devices with rigid housings. D1 is the first document to disclose a filter device in which the housing is formed from plastic sheets. This is made possible by using plastic bags which are originally

employed in the production of blood bags. For the blood bags, the problem of fluid leakage is rather restricted, so that it is natural to seal the plastic films with the ports sandwiched in-between. When this known structure is transposed to the production of flexible filter bags, the problem of leakage is more critical. This is then solved in D1 through the intermediary of a pliable frame for securing the filter media. Once the skilled person seeks to simplify the production of the flexible filter bags by moving the ports to be within the plastic housing sheets as proposed in D10, the pliable frame becomes redundant.

In the Board's judgment, however, the appellant's argument is flawed in that it is based on the reasoning of what the skilled person could have done but not what he would have done with the knowledge of D10. Indeed, the appellant has argued that D10 suggests, on the one hand, two options for arranging the ports and, on the other hand, that plural filter membranes can be installed in the external polyethylene bag (column 5, lines 44 to 45). D10 thus does not exclude the possibility for the ports to be arranged in the filter housings in the case that the filtration medium is a plurality of filter membranes or a filter pad. As is already indicated above, however, this particular embodiment is not disclosed in D10 (see item 2.2.6). Furthermore, the appellant has not indicated where in D1 or D10 a pointer can be found which would lead the skilled person to envisage such embodiment. The Board therefore holds that, without the benefit of hindsight, there is nothing in the available prior art which would motivate the skilled person to combine the teaching of D10 with that of D1 in such a way that would

necessarily result in a device comprising the positioning of the inlet and outlet ports and the integral bonding as in claim 1. In the absence of proof or at least convincing arguments to the contrary, the Board must conclude that the subject-matter of claim 1 involves an inventive step.

2.2.9 Re: distinguishing feature (iii)

Third filter layer of woven or knitted material

In view of the above finding, the Board holds it to be irrelevant as to whether the incorporation of a third filter layer as stipulated in claim 1 in lieu of the flexible rods as in D1 is obvious with respect to the available prior art.

3. The appellant has not raised any objection against the patentability of the remaining claims 2 to 12, nor can the Board see any reason for querying the patentability of these claims. The patent in suit can therefore be maintained with the claims as granted.

Auxiliary request for remittal and reimbursement

4. The appellant has argued that the wording of claim 1 would normally imply that the positioning of the ports along with the other technical features also stipulated in the preamble of claim 1, are known in combination in the art, here from D1. If the feature in question were indeed new, then the respondent should have made it clear by submitting an amended claim 1 which satisfies the requirements of Rule 29(1) EPC. The respondent having failed to file a correctly worded claim, the

appellant was therefore taken by surprise that the positioning of the ports should be decisive for the outcome of the opposition proceedings. The appellant has gone on to argue that, consequently, he did not have a fair chance for defending his case before the first instance.

4.1 It is undisputed that the decision to reject the opposition is based on the finding that the incorporation of the feature of the inlet and outlet ports being located in the flexible housing elements in claim 1 involves an inventive step. It is also irrefutable that the distinguishing feature in question is in the preamble of claim 1. The reasoning offered by the opposition division is that "the available prior art does not provide any hint towards locating the inlet/outlet ports in the flexible sheets, effectively piercing them. The same procedure of sandwiching these ports between the flexible layers is consistently used. In this respect it is noted that, although the opponent alleged during the oral proceedings that it is common praxis to secure tubing in the flexible parts of the bag, no substantiating evidence was provided." (see decision under appeal, pages 6 to 9, in particular page 7, penultimate paragraph and page 9, item 5.6).

4.2 The Board first wishes to remark that the objections raised by the appellant under Rule 29(1) EPC do not constitute a ground for opposition. Amendments to claim 1 for that reason alone would therefore be prejudiced by Rule 57(a) EPC.

Moreover, the difference between the arrangement of the ports in claim 1 and that in D1 is indicated in the respondent's letter of 16 August 2000 (page 6, item 5.1). Not only has the appellant acknowledged this fact in his letter dated 12 January 2001 but he has also indicated that prior art documents would be submitted to this respect (page 2, item 3, in particular last paragraph). The Board therefore cannot see how the appellant could have been taken by surprise at the relevance of the technical feature in question. Further to that, the Board notes that the oral proceedings before the opposition division took place on 9 March 2001, more than 6 months after the date of reply by the respondent. The appellant therefore could not (and did not) argue that he did not have enough time for preparing his case and file the pertinent prior art document(s). The decision as to whether or not to file and discuss document D10 at the opposition proceedings was thus his and not that of the other party. As a consequence, the Board holds that the appellant has had the opportunity to have his case examined upon the same facts by both instances, so that there is no justification for a remittal as foreseen in Article 111(1) EPC.

5. Pursuant to Rule 67 EPC, a reimbursement of appeal fee can only be ordered if at least the appeal is deemed to be allowable, which is not the case here.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

U. Bultmann

R. Spangenberg