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**Datasheet for the decision
of 22 October 2019**

Case Number: T 0834/14 - 3.2.02

Application Number: 03814606.4

Publication Number: 1585565

IPC: A61M1/28

Language of the proceedings: EN

Title of invention:

APPARATUSSES FOR PUMPING CASSETTE-BASED THERAPIES

Patent Proprietors:

Baxter International Inc.
Baxter Healthcare S.A.

Opponent:

(withdrawn)

Headword:

Relevant legal provisions:

EPC Art. 84, 123(2), 123(3)

Keyword:

Main request - clarity (yes)

Main request - added matter (no)

Main request - extension of protection (no)

Decisions cited:

Catchword:



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Case Number: T 0834/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 22 October 2019

Appellants: Baxter International Inc.
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(Patent Proprietor 2) Baxter Healthcare S.A.
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Representative: Potter Clarkson
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Respondent: withdrawn
(Opponent)

Representative: -

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted on 11 February
2014 revoking European patent No. 1585565
pursuant to Article 101(3)(b) EPC.

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	D. Ceccarelli

Summary of Facts and Submissions

- I. The appeal of the patent proprietors (the appellant) is against the decision of the Opposition Division dated 11 February 2014 to revoke the patent.
- II. Notice of appeal was filed by 7 April 2014. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 17 June 2014.
- III. In its statement of grounds (point 7), the appellant submitted that the Opposition Division may have made a substantial procedural violation, but it did not request reimbursement of the appeal fee and requested that the case not be remitted to the department of first instance for that reason alone. It also requested that in case of a remittal the composition of the Opposition Division be changed for reasons of equity.
- IV. By letter of 12 May 2015, the respondent/opponent withdrew its opposition.
- V. By its letter dated 11 September 2019, the appellant requested the maintenance of the patent on the basis of the main request filed by the same letter. The requests filed with the statement setting out the grounds of appeal were maintained as auxiliary requests in the same order.
- VI. Claim 1 of the main request reads as follows:

"A system (100) for performing dialysis comprising:
a patient line;
a disposable cassette (150,190) in communication with the patient line;

and an assembly (10) connected operably to the disposable cassette, wherein the assembly comprises:
a housing (20);
a pump actuator (32) coupled to the housing and in communication with a pumping portion of the cassette;
a valve actuation flow path (60) defined by the housing;
a plurality of valves (40) coupled to the housing and in communication with the valve actuation flow path and a valve portion of the cassette; and
an inlet (50) in communication with the valve actuation flow path,
wherein the housing defines a plunger aperture (66) for each valve, and wherein valve plungers (42) are positioned on an opposite side of the housing from the valves, the plungers disposed about the apertures."

VII. The appellant's arguments in relation to the objections of lack of clarity and added-matter are essentially those underlying the reasons of the present decision as set out below.

Reasons for the Decision

1. The appeal is admissible.
2. The invention

The invention claimed is about improvements to dialysis systems comprising disposable cassettes usable in haemodialysis and several kinds of peritoneal dialysis (CAPD, ADP, CFPD), [0018]. The improvement concerns the way part of the device (the assembly), which is in direct contact with the disposable cassette, is constructed. The assembly comprises an integrated "valve actuation flow path" which allows actuating

valves within the assembly which in turn displace plungers also within the assembly which open or close passageways in the disposable cassette used for the dialysis. The use of a housing in which there is an actuation flow path eliminates the need for multiple tubings.

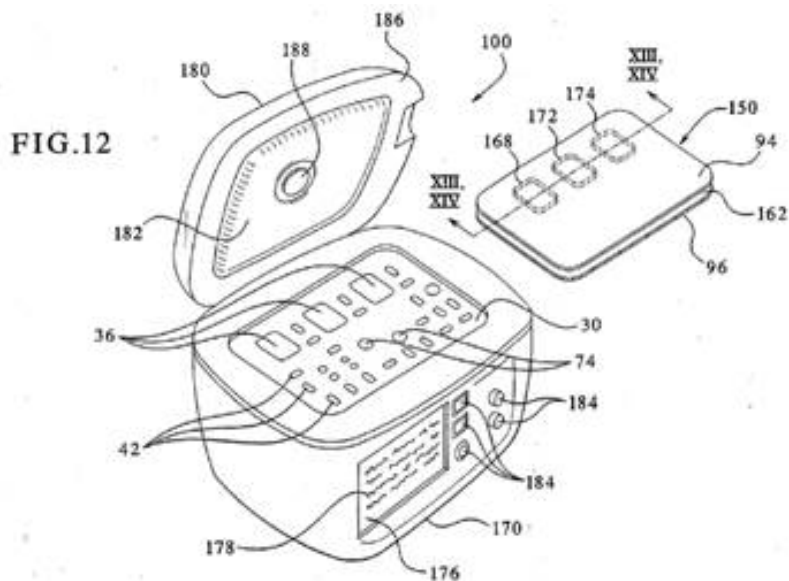
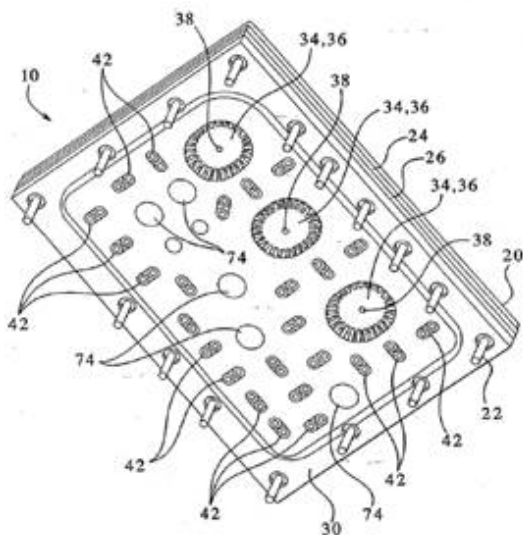
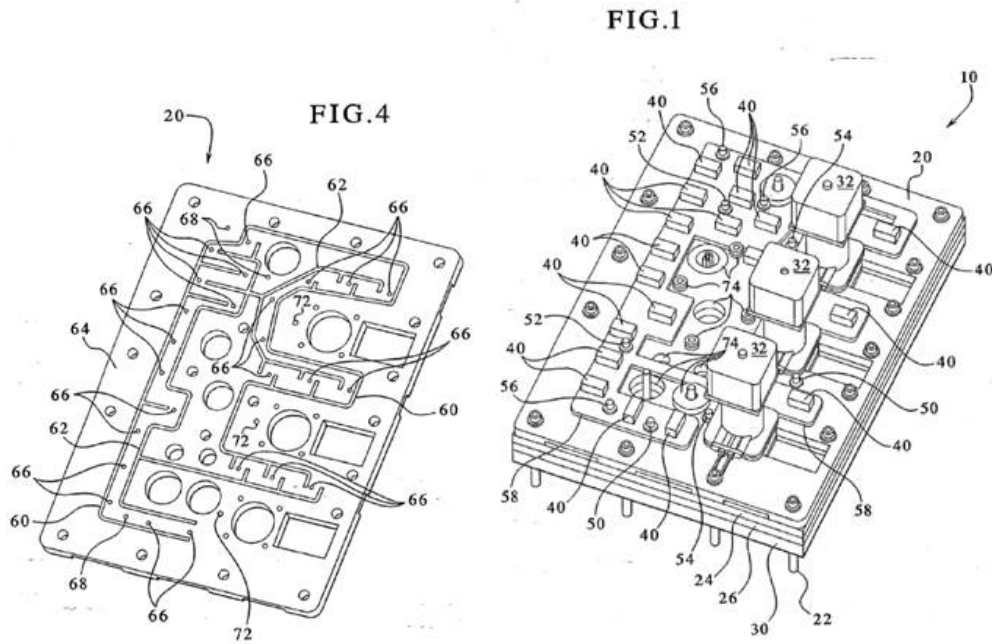


FIG.2





3. Clarity

In its decision, the Opposition Division considered under point 10.2.3:

*"It is common practise to raise a lack of clarity objection pursuant to Art. 84 EPC if the respective claim has one or more inconsistencies. In the present case, it is clear that the expression **the apertures** (plural) is not in line with the plunger **aperture** (singular) to which the former expression refers. This causes doubts about the real number of apertures defined by the housing..."*

This objection under Article 84 EPC is clearly addressed and overcome in claim 1 of the main request on file since "a plunger aperture (66) for each valve" replaces the former "a plunger aperture".

4. Added subject-matter

4.1 Valve actuation flow path

In paragraph 10.3.7 of the decision, the Opposition Division considered:

"... The Opponent correctly counter argued that the originally disclosed broad feature "flow path" (see for instance, claims 1, 17 and 25 as published) has been modified by adding a specific function, i.e. for actuating valves. This limitation neither has been literally disclosed and nor can it be derived by skilled person in a direct and unambiguous manner. As to the more specific disclosure of a flow path, the skilled reader takes from dependent claim 14 as published, for instance, that said flow path is a vacuum flow path. In view of the action on the valves enabled by said flow path it is originally disclosed (see page 17, lines 7 and 29) that vacuum is supplied through said flow path or channel (60). Alternatively (see page 15, line 19), said valves also can be electrically actuated. Thus, compared with the original disclosure, the amended expression "valve actuation flow path" generalizes the possible limitation of vacuum supply path for actuation of the valves without any basis in the original disclosure..."

The Board does not share this position for the following reason.

Claim 1 of the application as filed reads as follows:

"An assembly for operating a dialysis cassette comprising:
a housing;
a pump actuator in communication with the housing;
a flow path defined by the housing;

at least one valve coupled to the housing and in communication with the flow path; and an inlet in communication with the flow path." (emphasis added)

From the wording above, it is clear that what is claimed is an assembly for operating a dialysis cassette and not the dialysis cassette or even the combination of the cassette and the assembly. According to this claim, the assembly must have a housing, and a flow path must be defined by the housing, this flow path being in communication with a valve coupled to the housing. This means that on a fair reading, the valve is in communication with the flow path because it can be actuated through that flow path. This is in line with the desire to integrate the flow path for actuating the valves in the housing to avoid tubings as expressed on page 5, lines 17 to 24, of the application as filed:

"... the present invention provides an actuator assembly that operates with the disposable cassette. The assembly includes a housing that holds both the pump actuators and the valve actuators. The pump/valve manifold eliminates the need for separate valve manifolds. This in turn reduces significantly the amount of tubing and tubing connections that would otherwise have to be made between one or more valve manifolds and a pump actuator housing. The combination pump/valve manifold also conserves space and materials, allowing for a smaller, lighter and more cost effective dialysis machine."

It is therefore clear from a reading of claim 1 in the context of the application as filed as a whole that the flow path is for actuating the valves in the assembly. The Board therefore cannot see any unallowable

intermediate generalisation in changing the wording "flow path defined by the housing" to "valve actuation flow path defined by the housing". In the Board's opinion, the meaning is the same. While it is true that in the specific embodiment there is a negative pressure flow path and an atmospheric pressure flow path, this does not change that originally filed claim 1 was more general and gave a basis for the present wording. The way the flow path is arranged and how it is to be used is also confirmed in Figures 1 to 5, 10 and 11 and the corresponding parts of the description.

4.2 Beneath each valve

The last feature of the claim reads as follows:

"wherein the housing defines a plunger aperture (66) for each valve, and wherein valve plungers (42) are positioned on an opposite side of the housing from the valves, the plungers disposed about the apertures."

The Opposition Division considered that there was an intermediate generalisation in there not being an indication that the plunger apertures were beneath the valves as is indicated in claim 7 of the application as filed (claim 8 of the patent as granted).

The Board shares the appellant's view that "beneath" defines an orientation which does not exist when the assembly and cassette are in a vertical orientation as is possible according to page 7, lines 29 and 30, and page 30, lines 10 to 12. It is also not the case for the embodiment shown in Figure 10, in which there is one plunger on each side of the cassette 190. Moreover, it is technically self-evident that the orientation

does not play any role for the functioning of the device.

In addition, originally filed claim 17 reads:

"A system for operating a dialysis cassette comprising: an assembly including a housing defining a fluid flow path, a pump actuator and a plurality of valves coupled to the housing, the valves in communication with the fluid flow path; a pneumatic source in communication with the fluid flow path; a plurality of valve plungers operable with the valves; and a pump piston operable with the pump actuator." (emphasis added)

As can be seen, in this claim there is a general statement that the plungers are operable with the valves.

Also in the statement in the description concerning the brief description of Figure 5 (page 12, lines 4 to 6), there is no orientation statement concerning the plunger cavities:

"Fig. 5 is a perspective view of the opposing side of the valve/pump housing from the side illustrated in Fig. 4, the opposing side showing a plurality of valve plunger cavities."

The feature mentioned in claim 7 of the application as filed that the housing defines an aperture for each valve is now also present in claim 1 according to the main request.

4.3 Hence, Claim 1 satisfies the requirements of Article 123(2) EPC.

5. The Opposition Division further considered that dependent claims 2 and 15 of the requests then on file inserted added-matter and respectively extended the protection. This objection was based on the fact that the features of dependent claims 2 to 24 of the patent as granted could only define more precisely the assembly claimed in claim 1 and not more generally the system as claimed during the opposition proceedings.

Claim 25 of the patent as granted read as follows:

"A system (100) for performing dialysis comprising:
a patient line;
a disposable cassette (150, 190) in communication with the patient line; and
an assembly (10) as claimed in any one of claims 1 to 24 that is connected operably to the disposable cassette". (emphasis added)

This wording clearly implied that all the features of dependent claims 2 to 24 as granted could only define more precisely the assembly being part of the system and not more generally the system as such. Said differently, the additional features defined in claims 2 to 24 of the patent as granted could only be specifically part of the assembly, but not part of another component of the system for performing dialysis.

This problem is no longer present with the dependent claims of the main request since the expression "wherein the assembly (10)" has been added in the dependent claims (14, 15, 17, 18, 20) not directly referring to a feature of claim 1 clearly belonging to the assembly to make it clear that the feature which follows is a feature of the assembly.

Contrary to the Opposition Division's finding, the Board considers that, concerning claim 2, it is not necessary to include the assembly because the same word "inlet" is used with the same reference numeral "(50)" and, as in claim 1, the inlet is also said to be in communication with the flow path. Thus, it is clear that the same "inlet" as in claim 1 is meant, namely, the inlet of the assembly.

Hence, the set of claims according to the main request fulfils the requirements of Article 123(2) and (3) EPC.

6. Substantial procedural violation

In its statement of grounds, the appellant considered that given the objections raised for the first time during the oral proceedings and introduced into the proceedings by the Opposition Division, the appellant should have been given an opportunity to file amended requests. Moreover, since in the annex to the summons to the oral proceedings the Opposition Division did not comment on the feature "valve actuation flow path", the appellant considered that the Opposition Division did not see any problem with it, which was an additional reason to allow the filing of auxiliary requests. It also requested that in case of a remittal the composition of the Opposition Division be changed for reasons of equity.

As mentioned by the Opposition Division in its decision (point 11.2), the opponent had already objected to the feature "valve actuation flow path" in the notice of opposition (point II), and the appellant had not reacted by amending claim 1 to overcome that objection. In the Board's opinion, the appellant could have filed

an amended version of the claims to address this objection together with its reply to the notice of opposition, or at the latest before the oral proceedings.

Therefore, for that reason alone, the Board does not see any substantial procedural violation in forbidding the appellant to file additional requests during the oral proceedings. Despite that the Opposition Division accepted to consider other objections raised by the opponent only during the oral proceedings (points 10.2 (clarity) and 10.3.5 (support) of the decision), which would normally give a right to file a response to these new objections, the fact that there was one objection which had been in the file right from the start of the opposition proceedings and which could and should have been addressed earlier seems enough to justify the refusal to file new requests. Such a decision by the Opposition Division might be considered severe, but in the present situation it does not constitute a substantial procedural violation. Hence, also the composition of the Opposition Division does not have to be changed for reasons of equity.

7. Since the objections having led to the revocation have been overcome or found not well founded and the remaining requirements of the EPC have not yet been dealt with by the department of first instance, the Board exercises its discretion under Article 111(1) EPC to remit the case to the department of first instance for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated