

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen
(D) No distribution

**Datasheet for the decision
of 13 December 2012**

Case Number: T 2350/09 - 3.2.02

Application Number: 02079213.1

Publication Number: 1277485

IPC: A61M 1/28

Language of the proceedings: EN

Title of invention:

System for infusion of a plurality of solutions to a peritoneal cavity of a patient

Patent Proprietor:

Baxter International Inc.

Opponent:

Fresenius Medical Care Deutschland GmbH

Headword:

-

Relevant legal provisions:

EPC Art. 76(1), 111(1)

Keyword:

"Added subject-matter (yes - second to sixth auxiliary requests; no - 'First Auxiliary Request')"

"Admissibility of late filed 'First Auxiliary Request' - yes"

Decisions cited:

T 0284/94, G 0009/91

Catchword:

-



Case Number: T 2350/09 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 13 December 2012

Appellant: Baxter International Inc.
(Patent Proprietor) One Baxter Parkway
Deerfield, Illinois 60015 (US)

Representative: Dee, Ian Mark
Potter Clarkson LLP
The Belgrave Centre
Talbot Street
Nottingham NG1 5GG (GB)

Respondent: Fresenius Medical Care Deutschland GmbH
(Opponent) Else-Kröner-Strasse 1
D-61352 Bad Homburg (DE)

Representative: Herrmann, Uwe
Lorenz - Seidler - Gossel
Widenmayerstr. 23
D-80538 München (DE)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 18 November 2009
revoking European patent No. 1277485 pursuant
to Article 101(2) EPC.

Composition of the Board:

Chairman: E. Dufrasne
Members: M. Stern
P. L. P. Weber

Summary of Facts and Submissions

I. The proprietor lodged an appeal against the decision of the Opposition Division dispatched on 18 November 2009 revoking the European patent No. 1 277 485. The Opposition Division held that the ground for opposition under Article 100(c) EPC prejudiced the maintenance of the granted patent since the subject-matter of its claims 1, 7 and 8 extended beyond the content of the parent application as filed WO-A-97/07837 (D1).

II. A notice of appeal was filed by the proprietor on 9 December 2009. The fee for appeal was paid on 18 December 2009. A statement setting out the grounds of appeal was received on 26 March 2010.

III. In a communication under Article 15(1) RPBA dated 5 September 2012, annexed to the summons to oral proceedings, the Board expressed its provisional and non-binding opinion. In particular, the Board indicated that it was inclined to only rule on the grounds under Article 100(c) EPC (in combination with Article 76(1) EPC) on which the impugned decision was based, and to remit the case under Article 111 EPC to the Opposition Division for it to reach a first-instance decision on further grounds of opposition.

IV. Oral proceedings took place on 13 December 2012.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the second to fourth auxiliary requests filed on 26 March 2010 (with a letter wrongly dated 26 March 2009), or the fifth and sixth auxiliary

requests filed on 13 November 2012, or the "First Auxiliary Request" consisting of claim 1 filed during the oral proceedings of 13 December 2012 together with claims 2 to 11 of the patent as granted, in that order. The appellant expressly confirmed that the main request and the first auxiliary request which had been filed with the statement of grounds of appeal were withdrawn, and that the current "First Auxiliary Request" filed during the oral proceedings was a request subsidiary to the non-allowance of the sixth auxiliary request.

The respondent requested that the appeal be dismissed.

V.1 Claim 1 of the *second auxiliary request* reads as follows:

"1. A system (1) for infusion of a plurality of different solutions to a peritoneal cavity of a patient according to a pre-determined ratio, the system comprising:

means for storing each of the plurality of different solutions in a plurality of separate containers (10a, 10b, 10(n-1), 10n);

input means (52) for inputting an amount of each of the plurality of different solutions required for delivery to the peritoneal cavity of the patient;

supply valves (16a to 16c, 20a to 20c); and

pumping means for pumping each of the plurality of different solutions directly to the peritoneal cavity of the patient including first and second pumps (12, 14) each being connected to each of the plurality of containers via the supply valves in such a manner that either pump may be used to pump solution from each of said containers,

the input means and pumping means being capable of receiving and pumping variable mixing ratios of the plurality of different solutions."

V.2 Claim 1 of the *third auxiliary request* reads as follows:

"1. A system (1) for infusion of a plurality of different solutions to a peritoneal cavity of a patient according to a pre-determined ratio, the system comprising:

means for storing each of the plurality of different solutions in a plurality of separate containers (10a, 10b, 10(n-1), 10n);

input means (52) for inputting an amount of each of the plurality of different solutions required for delivery to the peritoneal cavity of the patient to achieve a desired dwell volume;

supply valves (16a to 16c, 20a to 20c);

pumping means for pumping each of the plurality of different solutions directly to the peritoneal cavity of the patient including first and second pumps (12, 14) each being connected to each of the plurality of containers via the supply valves in such a manner that either pump may be used to pump solution from each of said containers, and

control means (50) for determining whether the total volume of each different solution pumped by the pumping means is sufficient to achieve the pre-determined mixing ratio and the desired dwell volume."

V.3 Claim 1 of the *fourth auxiliary request* reads as follows:

"A system (1) for infusion of a plurality of solutions to a peritoneal cavity of a patient, the system comprising:
means for storing each of the plurality of solutions in a plurality of separate containers (10a, 10b, 10(n-1), 10n);
input means (52) for inputting an amount of each of the plurality of solutions required for delivery to the peritoneal cavity of the patient;
supply valves (16a to 16c, 20a to 20c); and
pumping means for pumping each of the plurality of solutions directly to the peritoneal cavity of the patient including first and second pumps (12, 14) each being connected to each of the plurality of containers via the supply valves in such a manner that either pump may be used to pump solution from each of said containers."

V.4 Claim 1 of the *fifth auxiliary request* reads as follows:

"A system (1) for infusion of a plurality of different solutions to a peritoneal cavity of a patient according to a pre-determined ratio, the system comprising:
means for storing each of the plurality of different solutions in a plurality of separate containers (10a, 10b, 10(n-1), 10n);
input means (52) for inputting an amount of each of the plurality of different solutions required for delivery to the peritoneal cavity of the patient to achieve a desired dwell volume;

supply valves (16a to 16c, 20a to 20c);
pumping means for pumping each of the plurality of different solutions directly to the peritoneal cavity of the patient including first and second pumps (12, 14) each being connected to each of the plurality of containers via the supply valves in such a manner that either pump may be used to pump solution from each of said containers, and
control means (50) for determining whether the total volume of each different solution pumped by the pumping means is sufficient to achieve the pre-determined mixing ratio and the desired dwell volume. [sic]
the input means and pumping means being capable of receiving and pumping variable mixing ratios of the plurality of different solutions."

V.5 Claim 1 of the *sixth auxiliary request* reads as follows:

"A system (1) for infusion of a plurality of different solutions to a peritoneal cavity of a patient according to a pre-determined ratio, the system comprising:
means for storing each of the plurality of different solutions in a plurality of separate containers (10a, 10b, 10(n-1), 10n);
input means (52) for inputting an amount of each of the plurality of different solutions required for delivery to the peritoneal cavity of the patient to achieve a desired dwell volume;
supply valves (16a to 16c, 20a to 20c);
pumping means for pumping each of the plurality of different solutions directly to the peritoneal cavity of the patient including first and second pumps each

comprising a pump chamber (12, 14) and each being connected to each of the plurality of containers via the supply valves in such a manner that either pump chamber may be used to pump solution from each of said containers by the application of negative and positive pressures to the pump chamber; and control means (50) for determining whether the total volume of each different solution pumped by the pumping means is sufficient to achieve the pre-determined mixing ratio and the desired dwell volume, the input means and pumping means being capable of receiving and pumping variable mixing ratios of the plurality of different solutions."

V.6 Claim 1 of the "*First Auxiliary Request*" reads as follows:

"A system (1) for infusion of a plurality of solutions to a peritoneal cavity of a patient, the system comprising:
means for storing each of the plurality of solutions in a plurality of separate containers (10a, 10b, 10(n-1), 10n);
input means (52) for inputting an amount of each of the plurality of solutions required for delivery to the peritoneal cavity of the patient; and
pumping means for pumping each of the plurality of solutions directly to the peritoneal cavity of the patient including first and second pumps (12, 14), a first set of supply valves (16a to 16c) operatively connected to the first pump and a second set of supply valves (20a to 20c) operatively connected to the second pump, each pump being connected to each of the plurality of containers via its supply valves in such a

manner that either pump may be used to pump solution from each of said containers."

Claims 2 to 11 of the "*First Auxiliary Request*" are dependent claims.

VI. The arguments of the appellant are summarised as follows:

(i) The parent application as filed, D1, provided a basis for reciting the feature of "supply valves" for both pumps as in claim 1 of the second to sixth auxiliary requests. Such a basis was given by independent claim 17 in combination with page 6, lines 28-32, and page 8, lines 16-26 referring to the embodiment of Figure 1, and in the embodiment of Figure 2.

(ii) Claim 1 of the "*First Auxiliary Request*" filed during oral proceedings was admissible since it involved allowable amendments in response to the arguments of intermediate generalisation which had been fully presented and discussed for the first time during the oral proceedings.

(iii) Claim 1 of the "*First Auxiliary Request*" remedied the objected deficiency of intermediate generalisation by adding the features that each of the two pumps was connected to the individual containers through a different set of supply valves. It was clear that the number of valves had to be equal to the number of containers.

(iv) The features of dependent claims 7 and 8 of the "First Auxiliary Request" had been disclosed on page 3, lines 25-28 of D1. The fact that claim 1 did not include the mixing means was irrelevant since the application made it clear that each of the embodiments of Figures 1 and 2 allowed both the direct infusion of fluids into a patient and the infusion via a container for mixing solutions prior to delivery (page 6, lines 28 to 32; page 9, lines 17 to 20; and page 15, lines 2 to 6).

(v) In view of the age of the patent and in the interest of procedural efficiency it was requested that the Board decides on all of the objections raised in the opposition without remittal of the case.

VII. The arguments of the respondent are summarised as follows:

(i) Claim 1 of the second to sixth auxiliary requests did not define that each of the two pumps accesses the individual containers through a different set of supply valves as disclosed for each of the embodiments of Figures 1, 2 and 5. Hence, claim 1 encompassed an undisclosed embodiment in which each of the two pumps is connected to each of the containers through just one common set of supply valves. Claim 1 constituted therefore an unallowable intermediate generalisation, as was explained in "Case Law of the Boards of Appeal", 6th Edition 2010, Chapter III.A.2, in particular in decision T 284/94.

(ii) Claim 1 of the "First Auxiliary Request" was filed during the oral proceedings and should not be admitted

in view of the lateness of its filing, in particular since the objections under Article 76(1) EPC had already been known to the appellant from the reply to its statement of grounds of appeal. Moreover, in view of the additional features introduced into the claim, the respondent would need to perform an additional search in order to properly address the questions of novelty and inventive step.

(iii) Claim 1 of the "First Auxiliary Request" was not allowable under Article 76(1) EPC since D1 did not disclose first and second "sets" of supply valves. Claim 1 constituted moreover an intermediate generalisation of the embodiments of Figures 1 and 2 of D1 since it did not specify that the number of supply valves in each set had to be equal to the number of containers. The claim would therefore encompass an undisclosed embodiment in which two containers were connected to one of the pumps through one and the same valve. Claim 1 also failed to specify that the two sets were different sets of supply valves.

(iv) Dependent claims 7 and 8 of the "First Auxiliary Request" were not allowable under Article 76(1) EPC. The features of these claims were disclosed on page 3, lines 25 to 28 of D1, but only in combination with the embodiment mentioned in the immediately preceding paragraph, ie in lines 15 to 24 of page 3, which comprised means for mixing fluids from two containers. Claim 1 defined however a different embodiment for direct infusion of solutions into the peritoneal cavity of the patient.

(v) In view of the fact that the present patent will expire in less than four years, the Board was asked to give a final decision not only on added subject-matter, but on all further outstanding matters, including novelty and inventive step, instead of remitting the case to the Opposition Division.

Reasons for the Decision

1. The appeal is admissible.

2. *The hierarchy of the requests*

The main request and the first auxiliary request which were filed with the statement of grounds of appeal were withdrawn during the oral proceedings (see point IV above). The current "*First Auxiliary Request*" as filed during the oral proceedings was requested by the appellant to be, irrespective of its heading, an auxiliary request for the case that the second to sixth auxiliary requests were found not to be allowable (see point IV above).

3. *Second to sixth auxiliary requests*

3.1 It is common ground among the parties that the system of claim 1 of the second request is primarily based on the system of independent claim 17 of the parent application as filed, WO-A-97/07837 (D1), further limited by defining that the system comprises *inter alia* the following highlighted features:

supply valves; and

pumping means for pumping each of the plurality of solutions **directly** to the peritoneal cavity of the patient **including first and second pumps each being connected to each of the plurality of containers via the supply valves in such a manner that either pump may be used to pump solution from each of said containers.**

- 3.2 The appellant considers that the parent application as filed, D1, provides a basis for these additional features on page 6, lines 28-32, and on page 8, lines 16-26 referring to the embodiment of Figure 1, and in the embodiment of Figure 2.
- 3.3 It is true that the embodiments of Figures 1 and 2 disclose pumping means which include two pumps (12, 14), each connected to each of a plurality of containers (10a, 10b, ... 10n) in such a manner that either pump may be used to pump solution from each of said containers (page 8, lines 18 to 22; page 9, lines 8 to 16; see also page 14, line 24 to page 15, line 6 referring to the embodiment of Figure 5).
- 3.4 However, the aforementioned description passages and Figures 1, 2 and 5 also make it clear that the first pump 12 pumps fluids through supply valves 16a, 16b, ... 16n, and that the second pump 14 pumps fluids through supply valves 20a, 20b, ... 20n. It is thus clear that each of the two pumps accesses the individual containers through a different set of supply valves.
- 3.5 The definition of claim 1, however, does not include this distinction between the respective sets of supply valves for each of the two pumps. The so defined subject-matter therefore also encompasses an

undisclosed embodiment in which each of the two pumps is connected to each of the containers through just one common set of supply valves. At least this undisclosed, technically feasible and relevant embodiment is thus added subject-matter extending beyond the content of D1, in particular its disclosed embodiments.

That is, the introduction into the claim of the general expression of "supply valves" in combination with the disclosed features of the two pumps, each connected to each of the containers, constitutes an intermediate generalisation which creates novel subject-matter as compared with the original disclosure ("Case Law of the Boards of Appeal", 6th Edition 2010, Chapter III.A.2; T 284/94, OJ 1999, 464; Reasons 2.1.6).

3.6 The Board consequently finds that claim 1 of the second auxiliary request contains subject-matter which extends beyond the content of the parent application as filed, contrary to the requirements of Article 76(1) EPC.

3.7 Since claim 1 of the third to sixth auxiliary requests does not contain any further limitation to the mentioned generalising definition of "supply valves", the above objection of added subject-matter under Article 76(1) EPC applies likewise to these auxiliary requests.

4. *"First Auxiliary Request"*

4.1 Admissibility

The respondent/opponent had indeed already indicated in its reply to the statement of grounds of appeal that

the incorporation of the feature of "supply valves" in claim 1 of the first (and subsequent) auxiliary request(s) filed with the statement of grounds of appeal would lead to an extension of subject-matter under Article 76(1) EPC. However, the detailed reasoning concerning the invoked intermediate generalisation had in fact only been presented in the respondent's letter in preparation of the oral proceedings and during the same.

The Board finds that it was therefore equitable to admit during oral proceedings what appeared to be a prima facie allowable claim in response to the arguments which had been fully presented and discussed for the first time during the oral proceedings. The Board also considers that the examination of the amendments of claim 1 with regard to the requirements of Article 76(1) EPC does not involve any undue complexity, a fact which the respondent did not contest.

The Board thus found claim 1 of the "First Auxiliary Request" to be admissible.

4.2 Article 76(1) EPC

4.2.1 Claim 1 of the "First Auxiliary Request" includes the feature that each of the two pumps are connected to each of the individual containers through a different set of supply valves, which was lacking in claim 1 of the second to sixth auxiliary requests as explained above under points 3.3 to 3.7.

4.2.2 Contrary to the objection raised by the respondent, the Board considers that even without an explicit disclosure in D1 it is clear that each of the two aforementioned disclosed groups of supply valves, that is valves 16a, 16b, ... 16n and valves 20a, 20b, ... 20n, respectively, constitutes a "set" of supply valves. Moreover, since each of these sets is identified in claim 1 by a different term ("first set of supply valves" and "second set of supply valves") it is clear that they represent two completely different sets of supply valves, rather than the same or even partially overlapping sets of valves as argued by the respondent.

4.2.3 The Board also considers that the number of valves in each set will invariably be equal to the number of containers in order that "either pump may be used to pump solution from each of said containers" as defined in claim 1. There is hence no need to explicitly include the definition of the number of valves in the claim.

The Board can also not follow the respondent's argument that the claim now encompasses a conceivable further embodiment in which two containers are connected to the pump through one and the same valve. The respondent was unable at oral proceedings to indicate a meaningful reason for envisioning such a construction in which the pump would be pumping through a single valve a mixture of the solutions which are contained in each container. Hence, in the view of the Board the envisioned construction seems technically contrived and unrealistic for the person skilled in the art.

4.2.4 As a consequence, claim 1 of the "First Auxiliary Request" fulfils the requirement of Article 76(1) EPC.

4.2.5 The respondent also raised the objection that the features of dependent claims 7 and 8 of the "First Auxiliary Request" were not disclosed in D1 in combination with the features of claim 1 of this request. Whilst the features of claims 7 and 8 are disclosed on page 3, lines 25 to 28 of D1, the respondent interpreted these features as being only disclosed in combination with the embodiment mentioned in the immediately preceding paragraph, ie in lines 15-24 of page 3, which comprises means for mixing fluids from two containers. Since claim 1 did not specify these means, the respondent concluded that it referred to a different embodiment than the one mentioned on page 3.

The Board does not share this view. The fact that claim 1 does not explicitly recite any mixing means does not imply that it defines a different embodiment. In fact, for each of the embodiments of Figures 1, 2 and 5, D1 mentions the possibility of a direct infusion of fluids into a patient and of an infusion via a container for mixing therein predetermined ratios of solutions prior to delivery. This is shown in the figures themselves and is further explained, for example, on page 6, lines 28 to 32; page 9, lines 17 to 20; and page 15, lines 2 to 6.

Hence, claims 7 and 8 of the "First Auxiliary Request" fulfil the requirement of Article 76(1) EPC.

5. Procedural matters

5.1 The decision under appeal only dealt with one of the invoked grounds of opposition, Article 100(c) EPC in combination with Article 76(1) EPC, leaving out any consideration of the further objections raised in the grounds of opposition, notably under Article 100(a) EPC, lack of novelty and of inventive step.

5.2 As stated in G 9/91, OJ 1993, 408 (point 18 of the Reasons), "[t]he purpose of the appeal procedure inter partes is mainly to give the losing party the possibility of challenging the decision of the Opposition Division on its merits. It is not in conformity with this purpose to consider grounds for opposition on which the decision of the Opposition Division has not been based."

Consequently, in the present case the Board summoned the parties to oral proceedings expressing its preliminary intention to limit the subject of the appeal to the examination of the objections under Article 76(1) EPC addressed by the impugned decision. This intention was also in line with the appellant's initial preference expressed in its statement of grounds of appeal, a preference which the appellant reverted just before the oral proceedings concurring then with the respondent's request that a final decision be made by the Board on all outstanding matters instead of remitting the case to the Opposition Division.

The invoked reason of procedural expeditiousness did not sway the Board towards remitting the case,

particularly in view of the further fact that the parties and the Board were confronted for the first time at the oral proceedings with the examination of an amended claim 1 incorporating new features taken solely from the description. Whilst these amendments render the claim allowable under Article 76(1) EPC, the claim now defines more specific subject-matter which has not been discussed by the parties during the appeal proceedings regarding novelty and inventive step.

5.3 The respondent expressed its concern regarding the lateness in the life of the present (divisional) patent when a final decision on the fate of the patent may possibly be reached. However, in this respect it should be noted that no request for an acceleration of the proceedings had been filed at any stage of the present proceedings.

5.4 The Board finds it therefore appropriate to exercise its discretion under Article 111(1) EPC not to conclusively decide on any further aspect than those mentioned above and to remit the case to the Opposition Division for further prosecution on the basis of the "First Auxiliary Request".

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