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**Datasheet for the decision
of 1 June 2018**

Case Number: T 0049/13 - 3.3.08

Application Number: 05713781.2

Publication Number: 1720999

IPC: C12Q1/37, C12Q1/26, G01N33/569

Language of the proceedings: EN

Title of invention:

Methods for detection of microbial contaminants in peritoneal dialysis solutions

Patent Proprietor:

Baxter International Inc.
Baxter Healthcare S.A.

Opponents:

McNab, Donald C.
Fresenius Medical Care Deutschland GmbH

Headword:

Method of manufacturing a peritoneal dialysis solution/BAXTER INTERNATIONAL, BAXTER HEALTHCARE

Relevant legal provisions:

EPC Art. 111(1), 113(1), 123(2)

EPC R. 103(1)(a)

RPBA Art. 12(4)

Keyword:

Substantial procedural violation - (no)

Amendments - allowable (no)

Decisions cited:

J 0007/83, J 0032/95, T 0823/96, T 2249/08, T 0160/09,

T 1340/10, R 0003/10

Catchword:



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Case Number: T 0049/13 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 1 June 2018

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 12 November
2012 revoking European patent No. 1720999
pursuant to Article 101(3) (b) EPC.**

Composition of the Board:

Chairman B. Stolz
Members: M. Montrone
 D. Rogers

Summary of Facts and Submissions

- I. An appeal was lodged by the patent proprietors (hereinafter appellants) against the decision of the opposition division to revoke European patent No. 1 720 999, entitled "*Methods for detection of microbial contaminants in peritoneal dialysis solutions*".
- II. The patent was opposed under Article 100(a) EPC on the grounds of lack of novelty and inventive step and under Articles 100(b) and (c) EPC.
- III. The opposition division held in the decision under appeal *inter alia* that claims 1, 11, 12 and 18 of the main request comprised added matter. The same applied to claims 1, 10, 11 and 16 of auxiliary request 1, claims 1 and 11 of auxiliary request 2, and claim 1 of auxiliary requests 5 to 10. It further took the view that claims 1 of auxiliary requests 3 and 4 contravened Article 123(3) EPC.
- IV. The appellants submitted with their statement of grounds of appeal a main request and eleven auxiliary requests. For ease of writing, the auxiliary requests that were filed as the "1st to 11th" auxiliary requests will be referred to as auxiliary requests 1 to 11, respectively. The main request and auxiliary requests 1 and 2 are identical to the main request and auxiliary requests 1 and 2 dealt with in the decision under appeal, while auxiliary requests 3 to 5 and 7 to 11 correspond to auxiliary requests 3 to 10 respectively all submitted with the letter of 27 January 2012 during the first instance proceedings. Auxiliary request 6 was filed for the first time during the appeal proceedings.

Claims 1 of the main request and auxiliary request 2 read:

"1. A method for manufacturing a peritoneal dialysis solution, the method comprising the steps of:

providing a glucose polymer;

performing a bioburden test for acidophilic thermophilic organisms to detect the presence of *Alicyclobacillus acidocaldarius*,

sterilising the glucose polymer,

adding a reagent to the glucose polymer wherein the reagent is capable of reacting with a peptidoglycan;

determining an amount of the peptidoglycan; and

using the glucose polymer to make the peritoneal dialysis solution if it is determined that a sufficiently low level of the peptidoglycan is present."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the feature "if it is determined that a sufficiently low level of the peptidoglycan is present" is replaced by the feature "if it is determined that the level of the peptidoglycan is 10 ng/mL or less".

V. In their replies to the appellants' statement of grounds of appeal, the opponents (hereinafter respondents I and II) maintained their objections raised during the first instance proceedings *inter alia*

with regard to Article 100(c) EPC. Furthermore, respondent I objected to the admission of auxiliary requests 3 to 11 into the appeal proceedings.

- VI. The parties were summoned to oral proceedings. In a communication pursuant to Article 15(1) RPBA, the parties were informed of the board's provisional, non-binding opinion on legal and substantive matters of the case. In particular, the board was of the provisional opinion that the decision under appeal did not suffer from a substantial procedural violation and that auxiliary requests 3 to 11 not be admitted into the appeal proceedings. Moreover, the board was not convinced by the appellants' arguments that *inter alia* the main request and auxiliary requests 1 and 2 did not comprise added matter. The board was thus minded to dismiss the appeal.
- VII. All of the parties replied to the communication. While the respondents announced their intention to attend the oral proceedings, the appellants announced that they would neither attend the oral proceedings nor be represented. Furthermore, the appellants declared that their requests - as submitted with their statement of grounds of appeal - were maintained.
- VIII. Oral proceedings took place on 1 June 2018, in the absence of the appellants. At the end of the oral proceedings the chairman announced the board's decision.
- IX. The submissions made by the appellants in writing, insofar as they are relevant to the present decision, may be summarised as follows:

Substantial procedural violation (Article 113(1) EPC)

The decision under appeal with regard to the main request suffered from a substantial procedural violation since the opposition division decided that the subject-matter of claims 1 to 18 lacked novelty, although the parties were not heard on this issue during the oral proceedings (see decision under appeal, section 16, headed "*Grounds for the Decision*"). In support of this argument, decision R 3/10 of 29 September 2011 was cited.

Main request (claims as granted)

Amendments (Article 100(c) EPC) - claim 1

The step of "sterilising the glucose polymer" referred to in claim 1 was disclosed in the priority application, not *expressis verbis* but implicitly. This was derivable from the fact that "*peritoneal dialysis solution (including all of its components, such as the glucose polymer) must undergo a sterilisation step in the preparation of the peritoneal dialysis solution. [...] Therefore, it is directly and unambiguously derivable by the skilled person, from the disclosure of the priority document and their common general knowledge, that any method for the preparation of a peritoneal dialysis solution includes a sterilisation step. Also, the sterilisation would apply to all of the components of the solution, including the glucose polymer*".

Auxiliary requests 1 and 2

Amendments (Article 123(2) EPC) - claims 1

Claim 1 of auxiliary request 1 included features of granted claims 6 and 17. Claim 1 of auxiliary request 2 corresponded to claim 1 of the main request.

- X. The submissions made by the respondents, insofar as they are relevant to the present decision, may be summarised as follows:

Substantial procedural violation (Article 113(1) EPC)

The decision under appeal with regard to the main request did not suffer from a substantial procedural violation, since the patent was revoked because it did not meet the requirements of Articles 123(2) and (3) EPC (see minutes, point 33). The discussion of novelty in the decision under appeal had no bearing on this finding, i.e. it did not play any decisive role since it rather appeared to be supererogatory and incidental. Thus, decision R 3/10 was of no relevance for the present case, since the underlying facts were different. In that case the parties were heard during the oral proceedings on novelty but not on inventive step. The subsequent decision acknowledged novelty, however not inventive step. Thus, contrary to the present case, the failure to hear the parties on the latter issue had a decisive impact on the decision.

Admission of auxiliary requests 3 to 11 (Article 12(4) RPBA)

Auxiliary requests 3 to 5 and 7 to 11 had all been replaced by amended auxiliary requests during the oral

proceedings before the opposition division (see minutes). In other words they were withdrawn by the appellants during the first instance proceedings and should thus not be admitted into the appeal proceedings (Article 12(4) RPBA). Likewise, new auxiliary request 6 should not be admitted into the appeal proceedings according to Article 12(4) RPBA, since the appellants neither justified its late submission nor provided reasons for admitting it.

Main request (claims as granted)

Amendments (Article 100(c) EPC) - claim 1

The process step of "*sterilising the glucose polymer*" had no basis in the application as filed, since the content of the priority application was not encompassed by the content of the application as filed.

Furthermore, the fact that peritoneal dialysis solutions comprise a glucose polymer and had to be sterile, did not mean that the glucose polymer had necessarily to undergo a separate sterilisation step as recited in claim 1. Rather the sterilisation could occur at different stages and conditions during the manufacturing process. Since the step was not disclosed in the application as filed, the claim comprised added matter.

Auxiliary requests 1 and 2

Amendments (Article 123(2) EPC) - claims 1

Claims 1 of auxiliary requests 1 and 2 also comprised the feature "*sterilising the glucose polymer*". Thus,

for the reasons set out for claim 1 of the main request, both requests contravened Article 123(2).

XI. The appellants requested that the decision under appeal be set aside and that the patent be maintained upon the basis of the main request, or alternatively, on the basis of one of auxiliary requests 1 to 11, all filed with their statement of grounds of appeal. Further it was requested that in view of the substantial procedural violation in the decision under appeal, the appeal fee be reimbursed and that the case be remitted to the opposition division, preferably in a different composition.

XII. Both respondents requested that the appeal be dismissed and that auxiliary requests 3 to 11 not be admitted into the appeal proceedings.

Reasons for the Decision

Substantial procedural violation (Article 113(1) EPC)

1. The appellant submitted that the decision under appeal suffered from a substantial procedural violation, since the opposition division decided that the main request lacked novelty, although the parties were not heard on this issue during the oral proceedings (see decision under appeal, sections 14.1 to 14.4 and 16).
2. The decision under appeal is 26 pages long. The first 19 pages assess the compliance of the main request, and of all ten auxiliary requests before the opposition division, with the provisions of Article 123(2) and (3) EPC. All claim requests were found to contravene

Article 123(2) and/or (3) EPC. On the next 4 pages of the decision under appeal, the opposition division assessed the compliance of the main request with the requirements of Articles 54 and 83 EPC. The main request was found to lack novelty and to comply with the requirements of Article 83 EPC. On the last three pages of the decision, under the title "*obiter dictum*", the opposition division assessed the compliance of the main request with Article 56 EPC and found that the main request involved an inventive step.

3. The minutes of the oral proceedings before the opposition division make no mention of any discussion of objections under Articles 54, 56 and 83 EPC. Appellants' allegation in this respect appears therefore to be correct.
4. The board has therefore to assess whether the opposition division's failure to hear the parties at the oral proceedings before deciding on objections raised on the grounds for opposition according to Article 100(a) and (b) EPC constitutes a substantial procedural violation.
5. The board considers that a "substantial procedural violation" is an objective deficiency affecting the entire proceedings (see decision J 7/83, reasons 12; OJ 1984, 211) which is to be determined on an objective basis (see decisions J 32/95, reasons 4.1; OJ 1999, 713, and T 0160/09, reasons 6).
6. There is no suggestion on file that the consideration of the claim requests in the light of Article 123(2) and (3) EPC was marred by a substantial procedural violation.

7. According to Article 101(2) EPC, if at least one ground for opposition prejudices the maintenance of the European patent, the opposition division shall revoke the patent in its entirety. Having determined that the main request comprised added matter, it was thus not necessary for the opposition division to return to the main request in order to consider if it might, nevertheless, comply with other provisions of the EPC.
8. Had the opposition division not considered the compliance of the main request with Article 54 EPC, its decision would have remained the same; the patent would have still been revoked.
9. It thus may have been an error on the part of the opposition division to decide on the compliance of the main request with the requirements of Articles 54 and 83 EPC, or not to have considered these issues under an *obiter dictum*. Nevertheless, an error which would not have led to a different outcome of the proceedings is not a substantial procedural violation, (see decisions T 2249/08, reasons 6.7; T 1340/10, reasons 1.6).
10. For these reasons, the facts underlying the present case are not comparable to those underlying case R 3/10. In that case, the parties were heard during the oral proceedings on novelty, but not on inventive step. The board in that case subsequently acknowledged novelty, but not inventive step, i.e. the failure to hear the parties on inventive step had a decisive impact on the decision, since it changed the outcome. Thus, the appellants cannot rely on decision R 3/10 to support their case.

11. The board therefore finds that the decision under appeal does not suffer from a substantial procedural violation.
12. In view of these considerations, neither the appellants request for the reimbursement of the appeal fee (Rule 103(1) (a) EPC) nor their request for remittal (Article 111(1) EPC) can be granted.

Main request (claims as granted)

Amendments (Article 100(c) EPC) - claim 1

13. Any amendment to the parts of a European patent application or to a European patent (description, claims and drawings) can only be made within the limits of what a skilled person would derive directly and unambiguously, either explicitly or implicitly, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the document as filed. An implicit disclosure in this context is what the person skilled in the art would consider as necessarily implied by the disclosure of the document as a whole or in other words the clear and unambiguous consequence of what is explicitly mentioned (see Case Law of the Boards of Appeal, 8th edition 2016 (hereinafter "CLBA"), II.E.1.2.1, II.E.1.2.2 and decision cited therein, in particular T 823/96).
14. In the following the references are to passages and claims in the international patent application WO 2005/093087 (hereinafter "the application as filed").

15. Claim 1 is directed to a method for manufacturing a peritoneal dialysis solution comprising several process steps, including "*sterilising the glucose polymer*".
16. It is common ground between the parties that the step of "*sterilising the glucose polymer*" has no explicit basis in the application as filed.
17. The issue to be assessed is thus whether or not the skilled person would derive such a process step from the implicit disclosure of the application as filed.
18. The essential argument of the appellants with regard to the step of "*sterilising the glucose polymer*" recited in claim 1, is that peritoneal dialysis solutions comprising a glucose polymer as one of their components, have to be sterile. This necessarily involves the sterilisation of each of its components, including the sterilisation of the glucose polymer.
19. Claim 1 is directed to a method for manufacturing a peritoneal dialysis solution. Assuming in the appellants' favour that the prepared final solution has to be sterile before it is administered *in vivo*, its sterilisation can be performed at different stages either during or at the end of the manufacturing process. In other words, the individual components as intermediate products of the final solution may either all be sterilised in separate process steps before they are mixed together to prepare the sterile peritoneal dialysis solution, or the final solution is sterilised only after all of its components have been mixed. Furthermore, mixtures of these sterilisation approaches are feasible, since it might be desirable to sterilise one or more of the individual components separately, including a sterilisation of the final solution after

mixing all of its components. Therefore, various alternative methods exist for producing a sterile peritoneal dialysis solution as a final product, which do not necessarily involve the individual process step of "*sterilising the glucose polymer*" cited in claim 1.

20. In view of these considerations, the board concludes that a method according to claim 1 comprising the step of "*sterilising the glucose polymer*" is not implicitly disclosed in the application as filed, since it is not the clear and unambiguous consequence of what is explicitly mentioned in the application as filed (see point 14 above).
21. Thus, the subject matter of claim 1 extends beyond the content of the application as filed (Article 100(c) EPC).

Auxiliary requests 1 and 2

Amendments (Article 123(2) EPC) - claims 1

22. Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the feature "*if it is determined that a sufficiently low level of the peptidoglycan is present*" is replaced by the feature "*if it is determined that the level of the peptidoglycan is 10 ng/mL or less*". Claim 1 of auxiliary request 2 is identical to claim 1 of the main request.
23. Therefore, claims 1 of both auxiliary requests comprise the process step "*sterilising the glucose polymer*", which is not directly and unambiguously derivable from

the application as filed for the reasons set out above with regard to claim 1 of the main request.

24. Consequently, auxiliary requests 1 and 2 contravene Article 123(2) EPC.

Admission of auxiliary requests 3 to 11 (Article 12(4) RPBA)

25. Auxiliary requests 3 to 11 were all filed with the appellants' statement of grounds of appeal. According to Article 12(1) and (2) RPBA, these requests are part of the appeal proceedings. The board, however, pursuant to Article 12(4) RPBA, has a discretion to hold inadmissible facts, evidence or requests, which could have been presented or were not admitted into the first instance proceedings.
26. Present auxiliary requests 3 to 5 and 7 to 11 correspond to auxiliary requests 3 to 10 respectively which were all filed by the appellants under cover of a letter dated 27 January 2012. These requests were however replaced by the appellants during the oral proceedings before the opposition division by amended auxiliary requests 3 to 10 (see minutes, points 7, 11, 14, 17, 20, 23, 27 and 30, respectively).
27. Although neither the minutes nor the decision under appeal state that auxiliary requests 3 to 10 filed with the appellants' letter dated 27 January 2012 were withdrawn, their withdrawal is implied by virtue of their replacement with amended requests 3 to 10 during the oral proceedings before the opposition division.
28. The primary function of an appeal is to give a judicial review of a decision taken by a department of first

instance. Thus, appeal proceedings are not an opportunity for a party to re-run the proceedings before the department of first instance (see CLBA, IV.E.4.1.4).

29. Several requests were filed but then withdrawn or abandoned during the first instance proceedings. By withdrawing these requests, the appellants prevented the opposition division from taking respective decisions on them. Further, despite explicit indications in the board's communication that it was minded not to admit auxiliary requests 3 to 11, the appellants have not submitted any reasons why they seek to re-introduce auxiliary requests 3 to 5 and 7 to 11 into the appeal proceedings.

30. Auxiliary request 6 was filed for the first time by the appellants with their statement of grounds of appeal. According to the appellants, its claims correspond to those of auxiliary request 1 in combination with those of auxiliary request 5 (see statement of grounds of appeal, point 1.2 and 4.7). Thus, as submitted by the appellants, it comprises subject matter which has never been presented in opposition proceedings (see statement of grounds of appeal, point 1.2). The board observes that the appellants have not given any reason why this request could not have been submitted during the first instance proceedings. Its admission therefore hinges on the question whether the appellants were in a position to make their submission earlier, and whether they could have been expected to do so under the circumstances.

31. Point 33 of the minutes shows that the appellants, after the chairman of the opposition division had announced that auxiliary request 10 was admitted into

the proceedings but did not meet the requirements of *inter alia* Article 123(2) EPC, did not submit any further requests.

32. Thus, the appellants were given the opportunity to file another amended claim request but did not avail themselves of this option. Furthermore, the appellants have not submitted reasons why they now seek to introduce auxiliary request 6 into the appeal proceedings.
33. In view of the above considerations, the board, exercising its discretion under Article 12(4) RPBA, does not admit auxiliary requests 3 to 11 into the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



L. Malécot-Grob

B. Stolz

Decision electronically authenticated