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Datasheet for the decision of 18 October 2011

Case Number: T 0611/09 - 3.3.02

Application Number: 99943881.5

Publication Number: 1107807

IPC: A61P 31/04, A61K 31/194

Language of the proceedings: EN

Title of invention:
Use of citrate in a catheter lock solution

Patentee:
Ash Access Technology, Inc.

Opponent:
Dirinco B.V.

Headword:
Catheter lock solution/ASH ACCESS TECHNOLOGY, INC.

Relevant legal provisions:
EPC Art. 54, 83
RPBA Art. 13(1)

Relevant legal provisions (EPC 1973):
EPC Art. 52(4)

Keyword:
"Main request and auxiliary requests 1-5 - sufficiency of disclosure (no): catheter lock solution not active within the human or animal body"
"Auxiliary request 6 - novelty (no): Swiss-type claim does not relate to use in a method referred to in Art. 52(4) EPC 1973"
"Auxiliary request 7 - admission (no): late-filed, amendments not forseeable"

Decisions cited:
G 0005/83, T 1286/05

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0611/09 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 18 October 2011

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 5 January 2009 concerning maintenance of European patent No. 1107807 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
R. Cramer

Summary of Facts and Submissions

I. European patent No. 1 107 807 based on application No. 99 943 881.5 was granted on the basis of 13 claims.

II. An opposition was filed against the patent. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC for amendments that contained subject-matter extending beyond the content of the parent application as filed.

III. The documents cited during the opposition and appeal proceedings included the following:

(1) Nephron 58, 119-120 (1991)
(23) Nephrol. Dial. Transplant 25, 1213-1217 (2010)

IV. The appeal lies from an interlocutory decision of the opposition division pronounced on 27 November 2008 and posted on 5 January 2009 maintaining the patent on the basis of the main request filed during the oral proceedings.

V. In said decision the opposition division decided that the requirements of Article 84 and Article 123(2) and (3) EPC were met. In connection with the requirements of Article 84 EPC, it was argued that the feature "for the treatment of substantial of infection" was clear, as it referred in a clear manner to prevention and/or prophylaxis of an infection. Moreover, said feature was not necessary for delimiting the subject-matter of the claim from the prior art. Furthermore, the invention

defined in the claims was sufficiently disclosed, as it was directly apparent that the intended treatment could be carried out with any patient having a catheter. Neither was it necessary to introduce the density or viscosity of the lock solution into the independent claims. As regards dependent claim 4, which comprised a viscosity range, the opposition division concluded that in principle it would be necessary to indicate a method for determining said viscosity. However, the requirements of sufficiency were nevertheless met, as the scope of the claims was defined by the independent claims, which were sufficiently disclosed. In addition, the subject-matter of the main request was novel, as document (1) did not disclose treatment or prevention of infections by citrate salt solutions. Regarding inventive step, the opposition division defined the provision of an additional application of a citrate salt solution as the problem to be solved vis-à-vis document (1), which had been identified as closest prior art. The solution in form of its application for the treatment of an infection or a substantial risk of infection implied an inventive step, as none of the additional cited documents rendered obvious the antibacterial efficacy of citrate in the very specific medical environment of a catheter.

VI. The opponent (appellant) lodged an appeal against that decision.

VII. With the reply to the statement of the grounds of appeal dated 30 November 2009, the respondent (patentee) filed auxiliary requests 1 to 5.

VIII. In a letter dated 12 April 2010, the appellant raised additional objections under Articles 84, 123(2) and 123(3) EPC.

IX. In the communication dated 6 October 2011, the board in its preliminary opinion expressed doubts that the claimed method concerned a therapeutic method according to Article 52(4) EPC 1973. Moreover, the board had doubts that the claimed invention was sufficiently disclosed, as treatment of an already existing infection did not appear to be feasible with a catheter lock solution comprising a citrate.

X. Oral proceedings were held before the board on 18 October 2011.

XI. The independent claims of the requests on file read as follows:

(i) Main request:

"1. The use of a citrate salt solution having a concentration to eliminate infection and to reduce the likelihood of subsequent infection for the manufacture of a medicament in the form of a catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter of a patient for the treatment of an infection or a substantial risk of infection related to the presence of the catheter wherein the lock solution comprises the citrate salt in a concentration range, in weight percent, of between 10% and 50%.

5. The use of a bactericidal component including greater than 50% by weight, based on the weight of the bactericidal component, of a citrate salt for the manufacture of a medicament in the form of a pharmaceutically acceptable catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter that has been surgically implanted into an animal for the treatment of an infection or substantial risk of infection related to the presence of the catheter."

(ii) Auxiliary request 1:

"1. The use of a sodium citrate salt solution having a concentration to eliminate infection and to reduce the likelihood of subsequent infection for the manufacture of a medicament in the form of a catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter of a patient for the treatment of an infection or a substantial risk of infection related to the presence of the catheter wherein the lock solution comprises the sodium citrate salt in a concentration range, in weight percent, of between 10% and 50%.

5. The use of a bactericidal component including greater than 50% by weight, based on the weight of the bactericidal component, of a sodium citrate salt for the manufacture of a medicament in the form of a pharmaceutically acceptable catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter that has been surgically implanted into an animal for the treatment of an infection or substantial

risk of infection related to the presence of the catheter."

(iii) Auxiliary request 2:

"1. The use of a citrate salt solution having a concentration effective to eliminate infection for the manufacture of a medicament in the form of a catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter of a patient for the treatment of an infection related to the presence of the catheter wherein the lock solution comprises the citrate salt in a concentration range, in weight percent, of between 10% and 50%.

5. The use of a bactericidal component including greater than 50% by weight, based on the weight of the bactericidal component, of a citrate salt for the manufacture of a medicament in the form of a pharmaceutically acceptable catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter that has been surgically implanted into an animal for the treatment of an infection related to the presence of the catheter."

(iv) Auxiliary request 3:

"1. The use of a sodium citrate salt solution having a concentration effective to eliminate infection for the manufacture of a medicament in the form of a catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter of a patient for the treatment of an infection related to the presence of the catheter wherein the lock solution comprises the

sodium citrate salt in a concentration range, in weight percent, of between 10% and 50%.

5. The use of a bactericidal component including greater than 50% by weight, based on the weight of the bactericidal component, of a sodium citrate salt for the manufacture of a medicament in the form of a pharmaceutically acceptable catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter that has been surgically implanted into an animal for the treatment of an infection related to the presence of the catheter."

(v) Auxiliary request 4:

"1. The use of a trisodium citrate salt solution having a concentration to eliminate infection and to reduce the likelihood of subsequent infection for the manufacture of a medicament in the form of a catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter of a patient for the treatment of an infection or a substantial risk of infection related to the presence of the catheter wherein the lock solution comprises the trisodium citrate salt in a concentration range, in weight percent, of between 10% and 50%.

5. The use of a bactericidal component including greater than 50% by weight, based on the weight of the bactericidal component, of a trisodium citrate salt for the manufacture of a medicament in the form of a pharmaceutically acceptable catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter that has been surgically implanted into an

animal for the treatment of an infection or substantial risk of infection related to the presence of the catheter."

(vi) Auxiliary request 5:

"1. The use of a trisodium citrate salt solution having a concentration to eliminate infection for the manufacture of a medicament in the form of a catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter of a patient for the treatment of an infection related to the presence of the catheter wherein the lock solution comprises the trisodium citrate salt in a concentration range, in weight percent, of between 10% and 50%.

5. The use of a bactericidal component including greater than 50% by weight, based on the weight of the bactericidal component, of a trisodium citrate salt for the manufacture of a medicament in the form of a pharmaceutically acceptable catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter that has been surgically implanted into an animal for the treatment of an infection related to the presence of the catheter."

(vii) Auxiliary request 6:

"1. The use of a citrate salt solution having a concentration to eliminate infection and to reduce the likelihood of subsequent infection for the manufacture of a medicament in the form of a catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter of a patient for the treatment

of a substantial risk of infection related to the presence of the catheter wherein the lock solution comprises the citrate salt in a concentration range, in weight percent, of between 10% and 50%."

Claim 5 is identical to claim 5 of the main request.

(viii) Auxiliary request 7:

"1. The use of a citrate salt solution having a concentration to eliminate infection and to reduce the likelihood of subsequent infection for the manufacture of a medicament in the form of a catheter lock solution for infusion into the lumen of an in-dwelling intravascular catheter of a patient for the treatment of a substantial risk of infection related to the presence of the catheter wherein the lock solution comprises the citrate salt in a concentration range, in weight percent, of between 20% and 50%."

Claim 5 is identical to claim 5 of the main request.

XII. The appellant's arguments can be summarised as follows:

Auxiliary requests 6 and 7 as well as document (23) were late filed and therefore not admissible. Moreover, the amendments made in auxiliary request 7 were a reaction to objections raised already in the first instance proceedings.

Regarding the question whether the method defined in the claims concerned a method of therapy, the appellant held that the antibacterial activity of the lock solution took place in the lumen of the catheter which

was outside of the human or animal body and therefore not suitable for the treatment of an already existing infection. As the claimed method was non-therapeutic, the intended uses mentioned in claim 1 did not constitute distinguishing features so that the lock solution disclosed in document (1) was detrimental to the novelty.

XIII. The respondent's arguments in connection with can be summarised as follows:
The filing of auxiliary requests 6 and 7 as well as of document (23) was the reaction of the board's communication issued less than two weeks before the oral proceedings and of arguments raised for the first time at the oral proceedings before the board. The amendments made in auxiliary requests 6 and 7 were simple and straightforward.

With regard to the question whether the method defined in the claims are directed to a therapeutic treatment, the respondent argued that the lock solution was applied to the lumen of an in-dwelling catheter, a part of which was inserted into the human or animal body. Said lumen was not completely separated from the blood so that there was an interaction of the lock solution with the blood. Making reference to the last three sentences of paragraph [0008] of the contested patent, the respondent argued that the tip of the catheter could be a source of infection which could be eliminated by the lock solution. As a consequence, the method defined in claims related to a therapeutic activity and was able to treat already existing infections.

XIV. The appellant requests that the decision under appeal be set aside and the European patent No. 1 107 807 be revoked.

XV. The respondent requests that the appeal be dismissed or, alternatively, that the decision under appeal be set aside and the patent be maintained on the basis of one of the auxiliary requests 1 to 5 filed with the letter of 30 November 2009 or auxiliary request 6 filed on the day of oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. Admission of auxiliary requests 6 and 7

These requests were filed at of the oral proceedings before the board and therefore at a very late stage of the appeal proceedings. The admission of these requests is therefore at the board's discretion and depends upon the overall circumstances of the case under consideration including the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy (see Article 13(1) of the Rules of Procedure of the Boards of Appeal (RPBA)).

2.1 Auxiliary request 6

Claim 1 of auxiliary request 6 is identical to claim 1 of the main request except for the deletion of the feature "for the treatment of an infection". This

amendment constitutes a reaction to the communication issued by the board on 6 October 2011 by fax, in which the board had raised doubts as to sufficiency of disclosure in connection with this feature (see point 6 of said communication). Taking into consideration that the appellant had only 12 days to react to this communication and that the amendment was such that the respondent was not taken by surprise, the board decided to admit auxiliary request 6 into the proceedings.

2.2 Claim 1 of auxiliary request 7 is identical to claim 1 of the main request except for the deletion of the feature "for the treatment of an infection" and for limiting the concentration range of the citrate salt for 10% to 50% to 20% to 50%. As far as the deletion of the treatment is concerned, see point 2.1 above. The limitation of the concentration range, however, is a reaction to objections already discussed at the oral proceedings before the opposition division and reiterated in the statement of the grounds of appeal, according to which a citrate concentration of 10% would not solve the technical problem (see the first two paragraphs of point 3.5.2 of the decision under appeal and the section "Inventive step [Art 56 EPC]" of the statement of the grounds of appeal). As a consequence, this amendment could have been made at a much earlier stage of the proceedings. Moreover, the limitation of the concentration range to 20% to 50% involved the introduction of a feature from the description, which at this late stage of the proceedings was not foreseeable for the respondent. As a consequence, the board decided not to admit auxiliary request 7 into the proceedings.

3. Admission of document (23)

At the oral proceedings before the board, the appellant submitted document (23) in order to demonstrate that the use of trisodium citrate as catheter lock solution should be restricted to authorised and skilled health-care professionals. Reference was made to the paragraph bridging the left-hand and right-hand columns on page 1214. In view of the fact that document (23) was post-published, filed at a very late stage of the appeal pro-ceedings and *prima facie* not relevant for the decision, the board decided not to admit it into the proceedings.

4. Main request

4.1 Preliminary considerations

Claim 1 of the main request, which is drafted in the "Swiss type" format, refers to two alternative uses of the lock solution, namely to the treatment of an infection and to the treatment of a substantial risk of infection, which in the view of the board is equivalent to a prevention.

4.1.1 Regarding therapy the board notes that according to the established jurisprudence of the boards of appeal, this term comprises any treatment designed to cure, alleviate, remove or lessen the symptoms of a disorder or malfunction or the human or animal body. This definition also includes a retardation in the progression of a disease, as for example in cancer therapy. All these aspects of therapy have one thing in common: the majority of the patients having undergone a

treatment must be in a better physical and/or mental state than those without a treatment.

A further important aspect in connection with therapy via medicaments is that the medicament is brought into contact with the body where it delivers the active agent(s) in order to obtain the desired pharmacological effect. Active agents exercising their activity outside the human or animal body (e.g. disinfection of surgical instruments in order to avoid infections) are not considered to be therapeutic.

4.1.2 In the present case it is therefore important to evaluate whether the lock solution exerts its antibacterial activity within the human or animal body or outside of it. According to paragraphs [0013] and [0024] of the contested patent, the lock solution is used for infusion into the lumen of an in-dwelling intravascular catheter, i.e. a catheter which is typically inserted into a vein or artery and therefore in intimate contact with the human or animal body. However, this does not necessarily mean that the lock solution is also directly in contact with or even active within it. Paragraph [0042] of the contested patent indicates that the lock solution, once infused into the lumen of the catheter, is allowed to remain until the catheter or lumen is desired to be accessed again. The lock solution can be removed from the catheter prior to infusion or removal of additional fluid for further treatment or, alternatively, it can be flushed directly into the patient without the necessity of removing it before infusing fluids for subsequent treatment. In the latter case, the lock solution enters of course into contact with the human

or animal body. However, in that case, the citrate in the lock solution is inactivated by calcium in the blood or calcium derived from body stores (see column 9, lines 18-20 of the contested patent) and can therefore not exert any therapeutic effect within the human or animal body. In this context, it is noted that it is irrelevant whether the bacteria are located at the tip of the catheter (see last three sentences of paragraph [0008] of the contested patent) and therefore very close to the lumen of the catheter or freely circulating in the bloodstream. The important point is that no antibacterial activity can take place within the human or animal body as a consequence of this inactivation. Therefore, the antibacterial activity will only take place in the lumen, which is a part of the catheter that is located outside of the human or animal body, which means that it is not therapeutic in the sense of Article 52(4) EPC 1973.

4.2 Sufficiency of disclosure

A logical consequence of the finding that the citrate containing lock solution does not show any therapeutic activity within the human or animal body is that it does not constitute a medicament which would be suitable for treating a bacterial infection of the human or animal body (see the second paragraph of point 4.1.1 above). It can certainly prevent or reduce the invasion of further microorganisms into the human or animal body by preventing contamination of fluids administered via the catheter as a preventive measure, but it is not able to inactivate pathogenic microorganisms which are already there. In other words, the citrate containing lock solution can at best

eliminate the source of an infection - which is comparable to the disinfection of surgical instruments - but it cannot alleviate or cure an already existing infection, which is claimed in claim 1 of the main request. As a consequence, the use claimed in claim 1 of the main request lacks sufficiency so that the requirements of Article 83 EPC are not met.

4.3 In view of this finding, an evaluation of the further objections raised by the appellant is not necessary.

5. Auxiliary request 1

Claim 1 of auxiliary request 1 is identical to claim 1 of the main request except that "citrate" was replaced by "sodium citrate". This modification can, however, not overcome the objections raised above in points 4.1 and 4.2. As a consequence, the invention defined in claim 1 of auxiliary request 1 does not meet the requirements of Article 83 EPC either.

6. Auxiliary request 2

Claim 1 of auxiliary request 2 is identical to claim 1 of the main request except that the feature "for the treatment of a substantial risk of an infection related to the presence of the catheter" was deleted. This modification can, however, not overcome the objections raised above in points 4.1 and 4.2. As a consequence, the invention defined in claim 1 of auxiliary request 2 does not meet the requirements of Article 83 EPC either.

7. Auxiliary request 3

Claim 1 of auxiliary request 3 is identical to claim 1 of the main request except that "citrate" was replaced by "sodium citrate" and that the feature "for the treatment of a substantial risk of an infection related to the presence of the catheter" was deleted. This modification can, however, not overcome the objections raised above in points 4.1 and 4.2. As a consequence, the invention defined in claim 1 of auxiliary request 3 does not meet the requirements of Article 83 EPC either.

8. Auxiliary request 4

Claim 1 of auxiliary request 4 is identical to claim 1 of the main request except that "citrate" was replaced by "trisodium citrate". This modification can, however, not overcome the objections raised above in points 4.1 and 4.2. As a consequence, the invention defined in claim 1 of auxiliary request 4 does not meet the requirements of Article 83 EPC either.

9. Auxiliary request 5

Claim 1 of auxiliary request 5 is identical to claim 1 of the main request except that "citrate" was replaced by "trisodium citrate" and that the feature "for the treatment of a substantial risk of an infection related to the presence of the catheter" was deleted. This modification can, however, not overcome the objections raised above in points 4.1 and 4.2. As a consequence, the invention defined in claim 1 of auxiliary request 5

does not meet the requirements of Article 83 EPC either.

10. Auxiliary request 6:

10.1 Novelty

According to G 5/83 (OJ EPO 1985, 64), a European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of manufacture as such does not differ from known processes using the same active ingredient (see point 23). However, this special approach to the derivation of novelty can only be applied to claims to the use of substances or compositions intended for use in a method referred to in Article 52(4) EPC 1973 (see point 21, last paragraph). If this is not the case, Swiss-type claims are according to the established jurisprudence of the boards of appeal read as claims defining a process of preparation (see T 1286/05 of 1 April 2008, points 2.3 and 2.4 of the reasons for the decision).

Making reference to the second paragraph of point 4.1.1 and to point 4.1.2 above, the board notes that the antibacterial activity of the lock solution takes place outside the human or animal body, so that it is not used in a method referred to in Article 52(4) EPC 1973. As a consequence, claim 1 of auxiliary request 6 concerns the preparation of a solution comprising between 10% and 50% of a citrate salt, which is suitable for being infused into the lumen of an in-

dwelling intravascular catheter and which is suitable for treating a substantial risk of infection related to the presence of the catheter. Document (1) discloses a catheter lock solution comprising 46.7% of sodium citrate. In view of this concentration, the board is convinced that the lock solution according to document (1) is suitable for being infused into the lumen of an in-dwelling intravascular catheter and for treating a substantial risk of infection related to the presence of the catheter. Moreover, the board notes that claim 1 does not contain any features defining the preparation of the lock solution and therefore includes any preparation process. As a consequence, the subject-matter of claim 1 of auxiliary request 6 is not novel over the disclosure according to document (1). The requirements of Article 54 EPC are therefore not met.

10.2 In view of this finding, an evaluation of the further objections raised by the appellant is not necessary.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

N. Maslin U. Oswald