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Datasheet for the decision of 28 November 2012

Case Number: T 1698/08 - 3.3.02

Application Number: 99959111.8

Publication Number: 1089738

IPC: A61K 31/54, A61P 31/00

Language of the proceedings: EN

Title of invention:
Antimicrobial compositions comprising taurolidine, citric acid and sodium citrate

Patentee:
ND Partners, LLC

Opponent:
ED. GEISTLICH SÖHNE AG FÜR CHEMISCHE INDUSTRIE

Headword:
Taurolidine lock solution/ND PARTNERS

Relevant legal provisions:
EPC Art. 112a, 100(c), 123(2), 106, 107, 108, 117, 114(2), 111(1)
EPC R. 99, 104, 106, 152
RPBA Art. 13, 12(4)

Keyword:
"Added subject-matter (yes):
main request, auxiliary requests 1-3, 5-7: singling out;
auxiliary request 8: unallowable generalisation"
"Added subject-matter (no): auxiliary request 11"
"Referral to the opposition division (yes): fresh case"

Decisions cited:
G 0003/97, T 0142/97

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1698/08 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 28 November 2012

Appellant: (Opponent)	ED. GEISTLICH SHÖNE AG FÜR CHEMISCHE INDUSTRIE Bahnhofstrasse 40 CH-6110 Wolhusen (CH)
Representative:	Barry, Robert Stewart Wilson Central Court 25 Southampton Buildings London WC2A 1AL (GB)
Respondent: (Patent Proprietor)	ND Partners, LLC One Joy Street Boston, MA 02108 (US)
Representative:	Kaiser, Jürgen Winter, Brandl, Fürniss, Hübner, Ross, Kaiser, Polte Partnerschaft Patent- und Rechtsanwaltskanzlei Alois-Steinecker—Strasse 22 D-85354 Freising (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 30 June 2008 rejecting the opposition filed against European patent No. 1089738 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman: M. C. Ortega Plaza
Members: H. Kellner
R. Cramer

Summary of Facts and Submissions

I. European patent No. 1 089 738, filed as application No. 99 959 111.8 based on international application PCT/US1999/011917 and published as WO 2000/001391, was granted with eleven claims.

Independent claims 1, 6 and 10 as granted read as follows:

"1. A pharmaceutical composition for inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device comprising:
(A) taurolidine
(B) citric acid, and
(C) tri-sodium citrate,
wherein said citric acid is present in a sufficient amount to bring the pH of the composition into the range of from 4.5 to 6.5.

6. A medical prosthetic device coated with the composition of any one of claims 1 to 5.

10. Use of a taurinamide derivative for the manufacture of a composition as defined in any one of claims 1 to 5 for inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device after said device has been inserted in a patient, comprising administration to said device a pharmaceutically effective amount of said composition."

II. Opposition was filed against the granted patent. The patent was opposed under Article 100(a) EPC for lack of inventive step and under Article 100(c) EPC because it

contained subject-matter which had not originally been disclosed.

The documents cited during the proceedings before the opposition division and the board of appeal include the following:

(9) WO-A-9828027

III. The appeal lies from the decision of the opposition division under Article 101(2) EPC, pronounced at oral proceedings on 12 June 2008 and posted on 30 June 2008.

The opposition division first noted that the objections pursuant to Article 100(c) EPC did not prejudice the maintenance of the claims as granted.

Moreover, for prior-art purposes the patent was not entitled to the priority of 2 July 1998. Consequently, in the opposition division's view, document (9) formed part of the state of the art under Article 54(2) EPC and had to be considered for the assessment of inventive step as closest prior art. However, document (9) did not mention citric acid and tri-sodium citrate and did not disclose the pH-value of the composition.

In consequence, the opposition division rejected the opposition.

IV. The opponent filed an appeal against that decision and submitted grounds of appeal.

V. In its reply to the grounds of appeal dated 25 March 2009 the respondent requested that the opposition division's decision be upheld (i.e. the maintenance of the patent as granted as the main request), auxiliarily that the patent be maintained with the sets of claims of the first, second and third auxiliary requests in the form of the sets of claims indicated in the proceedings before the opposition division.

In claim 1 of the first auxiliary request the passage "after said device has been inserted in a patient" is introduced into claim 1 as granted between "… medical prosthetic device" and "comprising: …".

In claim 1 of the second auxiliary request, the pH range of "4.5 to 6.5" is amended to read "5.0 to 6.5".

In claim 1 of the third auxiliary request, the amendments of both the first and second auxiliary requests are made. It thus reads:

"A pharmaceutical composition for inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device after said device has been inserted in a patient comprising:
(A) taurolidine
(B) citric acid, and
(C) tri-sodium citrate,
wherein said citric acid is present in a sufficient amount to bring the pH of the composition into the range of from 5.0 to 6.5."

VI. Summons to oral proceedings were sent to the parties on 13 August 2012.

VII. The board dispatched a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) dated 4 September 2012, expressing its preliminary opinion. The board pointed out *inter alia* that the set of claims as granted contained several independent claims which had to be regarded separately during the proceedings. The board also expressed a preliminary opinion in relation to the grounds of opposition pursuant to Articles 100(c) and 123(2) EPC respectively, in particular with regard to the issue of the omitted wording "after said device has been inserted in a patient". In addition, the parties' attention was drawn to the issue of added subject-matter regarding the multiple alternatives disclosed in the application as originally filed with respect to the antimicrobial compound, the acid and/or salt system and the pH of the composition (here and in the following, "application / description / claim as (originally) filed" or "original application / description / claim " or "original claim x" etc. refers to the application as published).

The board also expressed its preliminary opinion on entitlement to priority and on inventive step, which would have to be assessed with regard to document (9) alone or in connection with particular other documents.

VIII. The appellant, by letter of 29 October 2012, filed documents concerning the respondent's publications stating that there were clotting problems connected to the teaching of the patent in suit.

IX. With letter of 15 November 2012 the respondent questioned the authorisation of the appellant's previous and current representatives and the admissibility of the appeal.

It requested the board to ask the appellant for evidence that the professional representative who filed the appeal, Mr Matthews, had been validly authorised. Otherwise the appeal should be rejected as inadmissible, "as the Notice of Appeal has to be considered as not being filed".

In addition, the respondent submitted further auxiliary requests and filed eight sets of claims representing all the auxiliary requests to be regarded as in the proceedings at that time, namely the ones already filed in the proceedings before the opposition division (first to third auxiliary requests) and further amended claim sets according to the fourth to eighth auxiliary requests.

Arguments with respect to the board's communication were submitted, in particular that priority had to be acknowledged for claims with amended range for the pH-value (second and third auxiliary requests). Lastly, the respondent declared that the further requests were to be seen as a response to the communication. It described how the new claim sets were based on the claims as granted.

In addition, the respondent requested that the documents newly filed by the appellant not be admitted into the proceedings.

X. The board sent a brief communication dated 16 November 2012 in which it requested the appellant to clarify the issues in relation to the authorisation of its representatives.

XI. On 27 November 2012 the appellant's representative filed a copy of a letter of 15 April 2008 from the Lucerne Commercial Register Office ("Handelsregisteramt") with attached extract from the Swiss Commercial Register Ordinance ("Handelsregisterverordnung"), pages 4902 and 4903, as well as an internet extract from the Commercial Register of the Canton of Zurich (three pages) and argued that "at all material times Dr Peter Geistlich was "Mitglied" and had authority to solely sign for the Opponent".

XII. On 28 November 2012, oral proceedings took place before the board in the absence of the representative of the appellant. Duly summoned, it was not present. Upon telephone inquiry by the registrar it stated that it would not be attending the oral proceedings, and that it had notified the EPO of its absence by fax on 23 November 2012. As this fax never reached the file, the appellant resent the fax following the registrar's enquiry. According to this fax, the appellant said it did not wish to attend the oral proceedings, but would seek to rely only on its written submissions.

XIII. The respondent requested the board to reject the appeal as inadmissible as there were too many doubts with respect to the identity of the appellant and the authorisation of its representatives.

XIV. After deliberation the board announced that it had come to the conclusion that the appeal was admissible.

XV. Thereupon, the respondent raised a written objection under Rule 106 EPC. The objection reads as follows:

"Respondent herewith raises objections in accordance with R 106 EPC, with respect to evidence filed by Appellant, on 27 Nov 2012, in particular Handelsregisterauszug des Kantons Zürich, which bears on its last page the wording "Die obenstehenden Informationen erfolgen ohne Gewähr und haben keinerlei Rechtswirkung". Thus, these documents cannot be considered as means of evidence in the sense of Art. 117 resulting in a fundamental procedural defect in the sense of Art. 112 d)."

The respondent confirmed that it did not object to the admission of the letter of 15 April 2008 of the Lucerne Commercial Register Office and the extract from the Commercial Register Ordinance as evidence.

XVI. After deliberation it was announced by the board that the extract from the "Handelsregister des Kantons Zürich" filed by the appellant was admitted as evidence and that the objection under Rule 106 and Article 112a EPC was rejected.

XVII. With regard to the claim requests, during the proceedings the respondent withdrew its fourth auxiliary request and sought to file new requests, the seventh auxiliary request (revised version) replacing the seventh auxiliary request on file and additional

ninth to eleventh auxiliary requests (with a revised version of the eleventh auxiliary request replacing the eleventh auxiliary request filed before).

The fifth, sixth and eighth auxiliary requests, filed with letter of 15 November 2012 were admitted into the proceedings.

Claim 1 of the fifth auxiliary request is identical to claim 1 of the first auxiliary request; in the claim set claims 10 and 11 are omitted.

Claim 1 of the sixth auxiliary request corresponds to claim 10 as granted and is written in the Swiss-type format of a second medical use:

"Use of a taurinamide derivative for the manufacture of a composition for inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device after said device has been inserted in a patient comprising administration to said device a pharmaceutically effective amount of said composition wherein said composition comprises:
(A) taurolidine
(B) citric acid, and
(C) tri-sodium citrate,
wherein said citric acid is present in a sufficient amount to bring the pH of the composition into the range of from 4.5 to 6.5."

The wording of claim 1 of the eighth auxiliary request is:
"A pharmaceutical composition for inhibiting or preventing infection and blood coagulation in or near a

medical prosthetic device after said device has been inserted in a patient comprising:
(A) at least 13.3 g/l of taurolidine,
(B) 3.3 g/l of citric acid, and
(C) 6.7 g/l of tri-sodium citrate,
wherein said citric acid is added to adjust the pH range to 4.75 to 5.25."

Claims 1 of the ninth and tenth auxiliary requests correspond to claims 1 of the first and sixth auxiliary requests respectively in that they are amended by introduction of the words "as a lock solution" after "A pharmaceutical composition" in the ninth auxiliary request and after "Use of a taurinamide derivative for the manufacture of a composition" in the tenth.

XVIII. The revised seventh auxiliary request and the one single claim of the eleventh auxiliary request (also revised version) as filed during the oral proceedings were admitted into the proceedings, the ninth and the tenth were not.

Claim 1 of the seventh auxiliary request as filed during the oral proceedings corresponds to claim 6 as granted; it reads:

"A medical prosthetic device coated with a composition for inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device comprising:
(A) taurolidine
(B) citric acid, and
(C) tri-sodium citrate,

wherein said citric acid is present in a sufficient amount to bring the pH of the composition into the range of from 4.5 to 6.5".

The wording of the single claim of the eleventh auxiliary request in its revised version is:

"A pharmaceutical composition **as an aqueous antimicrobial lock solution** for inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device after said device has been inserted in a patient comprising:
(A) at least 13.3 g/l of taurolidine,
(B) **approximately** 3.3 g/l of citric acid, and
(C) 6.7 g/l of tri-sodium citrate,
wherein said citric acid is added to adjust the pH **of the composition to the** range **of** 4.75 to 5.25 (added wording with respect to the eighth auxiliary request in bold).

XIX. In addition to the arguments already set out under the previous points of this decision, the respondent's arguments may be summarised as follows:

On 20 May 2009 an authorisation had been filed by Ed. Geistlich Söhne AG für Chemische Industrie in Wolhusen, Switzerland, signed by Mr Peter Geistlich and authorising Mr Robert Barry as its representative. The authorisation was also dated 20 May 2009.

The respondent believed this authorisation was not valid as, according to an extract from the Commercial Register ("Handelsregisterauszug") of the Canton of Lucerne, the authority of Mr Peter Geistlich to sign on

behalf of the company had terminated on 24 April 2008 at the latest. It could even be deduced from the extract that his authority to sign had already ended on 12 July 2006, i.e. before the date the appellant had filed its opposition (5 February 2007). Therefore it was doubtful whether the professional representative who had filed the notice of appeal, Mr Matthews of Frank B. Dehn & Co, was validly authorised when filing the notice of appeal on 27 August 2008.

Thus, Mr Peter Geistlich had signed an authorisation although he was no longer authorised to sign on behalf of the appellant. There was also no evidence on file that Mr Matthews from Frank B. Dehn & Co. had been entitled to file the appeal. It was furthermore doubtful who had filed the appeal. The notice of appeal dated 22 August 2008 was filed on behalf of Ed. Geistlich Söhne AG für Chemische Industrie in Wolhusen, Switzerland. However, according to the appellant's letter of 27 November 2012 the Wolhusen branch office had closed in 2008. Also the Wolhusen branch could have been a different legal entity from the company registered in Schlieren, Canton Zurich. As for the internet extract from the Zurich Commercial Register filed with the same letter, this document had no value as evidence as it was stated at the end "Die obenstehenden Informationen erfolgen ohne Gewähr und haben keinerlei Rechtswirkung". Unlike the respondent, who had filed a certified extract from the Lucerne Commercial Register, the appellant had not filed a certified extract from the Zurich Commercial Register.

As to the merits of the patent in suit, the teaching of claims 1 of the main request and the first, second and

third auxiliary requests was directly and unambiguously derivable from different passages in the description as originally filed. In particular, all relevant features were derivable from preferred features set out in the text on the single page 21, with the additional possibility to choose taurolidine from particularly mentioned taurinamide derivatives taurolidine and taurultam, taurolidine being mentioned in original claim 3 and being used in the examples.

All these features were in addition supported by the examples as a whole.

In particular

- pH 5 as lower limit of the pH range in each of claims 1 of the second and third auxiliary request was disclosed as the result of example 5 and
- the eighth and the revised eleventh auxiliary requests related to example 2.

In each of claims 1 of the eighth and the revised eleventh auxiliary requests the amendment of 13.3 g/l taurolidine to "at least 13.3 g/l" did not represent added subject-matter since the skilled person clearly recognised in the light of the description that an antimicrobial effect would also be present with higher concentrations of the antimicrobial substance. The word "approximately" before "3.3 g/l of citric acid" was left out in the eighth auxiliary request in order to prevent any objection of lack of clarity. The fixed concentration of 3.3 g/l citric acid was not in contradiction with a pH range of 4.75 to 5.25 to be adjusted, because usually using 3.3 g/l citric acid together with 6.7 g/l of tri-sodium citrate would

result in a pH value in the range as indicated. If necessary, the feature "wherein said citric acid is added to adjust the pH range to 4.75 to 5.25" would mean that citric acid exceeding the 3.3 g/l citric acid concentration could be used to reach the pH value as foreseen in the claim.

XX. The written submissions of the appellant as far as relevant for the present decision can be summarised as follows:

The headquarters of Ed. Geistlich Söhne AG für Chemische Industrie are in Schlieren, Canton Zurich. In Wolhusen, Canton Lucerne, there had been a branch office of the same company which had closed in 2008 "and a part of its operations were transferred to another company". As shown by the internet extract from the Zurich Commercial Register, Mr Peter Geistlich's authority to sign on behalf of the company had never been terminated.

With regard to the patent in suit, the omission of the wording "after said device has been inserted in a patient" was objected to with regard to Article 100(c) EPC.

XXI. The appellant (opponent) according to its written submissions requested that the decision under appeal be set aside and that the European patent No. 1 089 738 be revoked.

XXII. The respondent (patentee) requested that the appeal be declared inadmissible. Alternatively it requested that the appeal be dismissed. More alternatively it

requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the auxiliary requests 1, 2, 3, 5, 6 or 8 filed with the letter of 15 November 2012, or auxiliary requests 7, 9, 10 or 11 (7 and 11 in revised version) filed at the oral proceedings on 28 November 2012.

It further requested that the document entitled "Handelsregister des Kantons Zürich" filed with the appellant's letter of 27 November 2012 not be admitted into the proceedings.

Reasons for the Decision

1. *Admissibility of the appeal*

1.1 *Authorisation of the representative having signed the notice of appeal*

The opposition was filed on behalf of Ed. Geistlich Söhne AG für Chemische Industrie in Wolhusen, Switzerland, by Mr J.C. Marsden of Frank B. Dehn & Co., who was at the time a professional representative before the EPO. At the oral proceedings before the opposition division, Mr D.P. Matthews from Frank B. Dehn & Co. took over the representation of the opponent. Mr Matthews is also a professional representative before the EPO. It was Mr Matthews who subsequently filed an appeal on behalf of the opponent on 27 August 2008. Mr Matthews continued to be registered as representative of the appellant until the filing of the authorisation for Mr Barry on 20 May 2009.

According to Rule 152(1) EPC and the decision of the President of the EPO dated 12 July 2007 on the filing of authorisations (OJ EPO, Special edition 3/2007, No. L.1), a professional representative is only required to file an authorisation in particular circumstances.

Thus, if none of these circumstances apply, the professional representative is deemed to be authorised to perform all procedural acts on behalf of a party, up to the moment that the EPO is informed of the termination of his authorisation (Rule 152(8) EPC). In the present case, the filing of the authorisation for Mr Barry on 20 May 2009 was deemed to be the moment that the EPO was informed of the termination of the authorisation of the previous representative, Mr Matthews.

Up until that moment there had been no necessity for Mr Matthews to file an authorisation, nor for the EPO to require him to do so. The change in representatives during the proceedings before the opposition division involved representatives belonging to the same association, and there was no reason to doubt Mr Matthews' entitlement to act (decision of the President, *ibid*, Articles 1(2) and (3)) and consequently no reason to request the filing of an authorisation.

Even at the time of the decision before this board there is no such reason, because doubts in the sense of Article 1(3) of the decision of the President cannot be based on the simple allegation that the previous or subsequent representative might have been authorised by

a person who was possibly not entitled to act on behalf of the party at the time the authorisation was given. In the current case, there is no link between the authorisation of Mr Barry and the authorisation of Mr Matthews but the company in whose name either of them acts.

1.2 *Identity of the appellant*

As far as identity of the appealing opponent is concerned, both the opposition and the appeal were filed on behalf of Ed. Geistlich Söhne AG für Chemische Industrie in Wolhusen, Switzerland. With its letter of 15 November 2012 the respondent filed a certified extract from the Commercial Register of the Canton of Lucerne, that lists the above-named company as a "Zweigniederlassung". According to the extract the principal place of business of Ed. Geistlich Söhne AG für Chemische Industrie is in Schlieren, located in the Canton of Zurich, and therefore, both offices belong to the same legal entity.

Even if the appellant's representative stated in his letter of 27 November 2012 that in 2008 the Wolhusen branch office was closed, the board is satisfied that this statement is not correct, as the branch office is obviously still registered in the Lucerne Commercial Register (see column "Ei", where number 12 marks the amended registration of the branch in Wolhusen starting from 24 April 2008 under "Firma oder Name der Zweigniederlassung (ZN)" (company or name of the branch office)), and since there is an obvious contradiction with the representative's statement "and a part of its operations were transferred to another company" and

Mr Barry's authorisation being sent to the EPO from the Wolhusen address on 20 May 2009, submitted by a person mentioned in the register of Lucerne under the branch office in Wolhusen as authorised to sign together with another person ever since 4 February 2000 (see certified copy, the last two tables).

Consequently, there are no doubts with respect to the true identity of the appellant, being an "Aktiengesellschaft" with a principal office in Schlieren and a branch office in Wolhusen. From the fact that both offices bear the same name of the Aktiengesellschaft it is already obvious that they belong to the same legal entity. The fact that a "Zweigniederlassung" is not a separate legal entity under Swiss law follows also from Article 109 of the Commercial Register Ordinance, which speaks about the registry of a "Zweigniederlassung einer Rechtseinheit".

Whether or not the Schlieren address should have been used rather than the Wolhusen address when filing the notice of appeal is immaterial, as the identity of the appellant is clear and can be verified through both addresses. The Lucerne Commercial Register indicates under what number the principal office is registered in Zurich (see "weitere Angaben zum Hauptsitz" (further indications regarding the principal office)).

1.3 Since, for these reasons, the appeal complies with the provisions of Articles 106 to 108 and Rule 99 EPC, it is admissible.

1.4 *Authorisation of Mr Barry*

The authorisation of Mr Barry has been signed by Mr P. Geistlich on behalf of Ed. Geistlich Söhne AG für Chemische Industrie. The appellant, to the satisfaction of the board, has filed evidence why Mr Peter Geistlich was no longer listed in the Lucerne Commercial Register as entitled to sign on behalf of the Wolhusen branch. From the letter of the Commercial Register of 15 April 2008 and Article 110 of the Commercial Register Ordinance it is to be concluded that Mr Peter Geistlich had to be deleted from the Lucerne Commercial Register **as he was also listed as authorised to sign in the Register entry of the principal office** (see "Hinweis" on page 2 of the letter, second paragraph and arguments under point 1.2 of this decision).

The board therefore has no reason to doubt the validity of the authorisation of Mr Barry.

In addition, the (uncertified) extract from the Zurich Commercial Register filed by the appellant does not contradict the conclusions of the board and even gives plausible confirmation that Mr Peter Geistlich was authorised to sign on behalf of the "Aktiengesellschaft" with "Einzelunterschrift".

1.5 *Admission of the extract from the Zurich Commercial Register*

Although the respondent - until the announcement of the admissibility of the appeal - had not objected to the admission of the documents filed with the appellant's letter of 27 November 2012, the day before the oral

proceedings, after this announcement it objected to the admission of this extract as it states at the end "Die obenstehenden Informationen erfolgen ohne Gewähr und haben keinerlei Rechtswirkung", which in its opinion had the consequence that the extract could not be considered as a means of evidence in the sense of Article 117(1) EPC.

Article 117(1)(c) EPC lists "production of documents" as a valid means of giving evidence, whereby it is to be noted that the list in Article 117(1) EPC is not exhaustive, as can be deduced from the words "shall include". A refusal to admit such a piece of evidence can therefore not be based on Article 117(1) EPC.

While it has been accepted in the jurisprudence of the boards of appeal that EPO departments have some discretion in admitting evidence, e.g. where the evidence is unnecessary or of no relevance (cf. T 142/97, OJ EPO 2000, 358, Reasons No. 2.2.), the main legal basis for refusing the admission of evidence are the provisions dealing with the late filing of evidence (Article 114(2) EPC, Articles 12(4) and 13 RPBA). The present piece of evidence cannot be considered as having been filed late, as it was filed in direct response to arguments the respondent had raised for the first time in its letter of 15 November 2012.

There is also no other reason for the board to exercise its discretion to refuse to admit the evidence, as it can neither be said that it is irrelevant nor that it is unnecessary. A refusal to admit can in any case not be based on statements in the document with respect to the accuracy of the facts it contains. Such statements

relate to the probative value of a document. Based on the principle of free evaluation of evidence (G 3/97, OJ EPO 1999, 245, Reasons No. 5), the board is free in assessing to what extent the information in a document is credible, whereby such statement may play a role.

The board has been in a position to establish that the appeal is admissible without relying on the data in the document in question (extract from the Zurich Commercial Register), but has at the same time found no indication in the document that would cast any doubts on the finding of admissibility. It has also found no indication that would lead to doubts as to Mr Peter Geistlich's authority to sign the authorisation for Mr Barry. This document rather confirms all the findings by the board as far as based on the evidence filed by the respondent himself, and the board is convinced that its content is credible at least to that extent.

2. *Objection under Article 112a EPC*

The board has interpreted the respondent's objection (see last line of the written statement) that admitting the internet extract from the Zurich Commercial Register resulted in a "fundamental procedural defect in the sense of Article 112 d)" as referring to Article 112a(2)(d) EPC, since there is no other logical meaning (this interpretation was recorded in the minutes of the oral proceedings to which there was no objection by the appellant).

However, Article 112a(2)(d) states that the fundamental procedural defect must be one that has been defined in

the Implementing Regulations. The corresponding provision in the Implementing Regulations is Rule 104. The board has however neither failed to arrange for oral proceedings, nor decided on the appeal without deciding on a request relevant to the decision. Nor did any other procedural defect within the meaning of Article 112a(2) EPC occur.

Thus, even if there had been reasons to refuse to admit the document, admitting it into the proceedings would not amount to a fundamental procedural defect within the meaning of Article 112a(2)(d) EPC. Therefore, the objection under Rule 106 and Article 112a EPC must be rejected.

3. *Admissibility of the claim requests*

3.1 The amended claims of auxiliary requests 1, 2 and 3 were filed in the proceedings before the opposition division, repeated with the respondent's reply to the grounds of appeal and identically filed with letter of 15 November 2012. In this situation they are admitted into the proceedings.

3.2 The filing of amended claims as auxiliary requests 5, 6 and 8 with letter of 15 November 2012 and as auxiliary requests 7 and 11 (both in their finally revised version) at the oral proceedings on 28 November 2012 is recognised as a *bona fide* attempt to respond to the arguments set out in the communication of the board and during the oral proceedings. These claims are therefore admitted into the proceedings.

3.3 Auxiliary requests 9 and 10, filed at the oral proceedings on 28 November 2012 *prima facie* did not overcome the objections discussed in the communication of the board and during the oral proceedings and opened new issues for discussion in relation to Article 123(2) and 84 EPC. Therefore, they are not admitted into the proceedings.

4. *Claim 1 of the main request (claims as granted); Article 100(c) EPC*

4.1 Claim 1 as granted relates to

- a pharmaceutical composition …

comprising

- (A) taurolidine
- (B) citric acid, and
- (C) tri-sodium citrate,
- wherein said citric acid is present in a sufficient amount to bring the pH of the composition into the range of from 4.5 to 6.5.

4.2 The generic disclosure on page 21, line 1 to page 23, line 7 of the application as filed, which comes as close as possible to the claimed subject-matter and, therefore, in this respect represents the essential over all content of the application as originally filed, relates to

- a composition (partly defined by way of a product-by-process "… so as to produce a pH of the ultimate composition …")

comprising

- antimicrobial taurinamide derivatives as component (A)
- combined with a biologically acceptable acid (component B in claim 1 as granted)

or

- biologically acceptable salt thereof (component C in claim 1 as granted)
- so as to produce a pH for the ultimate composition that is **no higher than 7, preferably in the range of from about 3.5 to about 6.5**, more preferably in the range of from about 4.5 to about 6.5 (page 21, lines 1 to 5 with board's emphasis; this passage was also cited by the respondent in writing and during the oral proceedings as the basis for the disclosure of claim 1 of the main request).

4.2.1 The particular component (A) taurolidine is mentioned in the examples and in original claim 3; in claim 4, however, taurultam is mentioned as alternative component (A).

4.2.2 In the text following the cited passage on page 21, with respect to the acid component (B) it is set out on the same page of the original description that "A blood anticoagulating amount of an acid selected from the group consisting of citric acid, phosphoric acid, ethylenediaminetetraacetic acid (EDTA), … and biologically acceptable salts thereof is preferred."

The salt represents component (C). The text continues:

"It is preferred that the acid employed in the practice of the present invention be …, particularly citric acid or EDTA. It is more preferred that the acid be citric

acid and most preferred that it be used in combination with a citrate salt, e.g., sodium citrate, since, in addition to its pH lowering and anticoagulation capabilities, it is also known to be an antiseptic at the 3% level" (page 21, lines 12 to 20).

In this context it is to be noted that citric acid / sodium citrate are connected to "a blood anticoagulating amount" and to be "an antiseptic at the 3% level."

In addition, in the application as filed it is stated that "the disodiumsalt of EDTA and sodium citrate" are "most preferred" (page 22, line 17) and "Where, as is preferred, trisodium citrate and citric acid are employed in the practice of the present invention, the trisodium citrate will typically be used in a concentration range of from about 5 to about 50 grams per liter" (page 23, lines 4 to 6).

Therefore, the disclosure relating to a buffer system (combination of components (B) and (C)) in the taurolidine- **or** taurultam-containing composition is that among other possibilities EDTA **or** citric acid together with their sodium salts can be used; moreover, the particular use of sodium citrate is connected to "the 3% level" (page 21, line 20) and/or to a concentration range of from about 5 to about 50 grams (page 22, lines 4 to 6).

4.2.3 With respect to the pH range of the claimed composition it is to be taken into account that according to page 22, lines 18 to 22 of the application as originally filed "The acid and/or salt will be used in

a concentration effective to bring about the desired anticoagulation effect and, at the same time, bring about, or help to bring about, an **appropriate pH for biological use**. Typically, the combined antimicrobial and anticoagulant composition of the present invention will have a **pH in the range of from about 3.0 to about 7**, preferably from about 3.5 to about 6.5 and, most preferably from about 4.5 to about 6.5" (emphasis by the board). Thus, the generic disclosure for the pH ranges on page 22 is not identical to the definitions given for pH ranges on page 21.

The application as filed further states that

- "taurolidine activity increases with decreasing pH in the range of from pH 7.0 to pH 5.0" (lines 2 and 3 on page 22 of the original description) and, finally,
- the pH range in example 2 is 4.75 to 5.25.

Therefore, a particular range of pH-values to be chosen as inevitably unique is not to be found in the application as originally filed.

4.2.4 Under these circumstances, the person skilled in the art, taking the overall content of the application as originally filed, cannot come to the conclusion that the subject-matter as claimed in claim 1 of the main request would be directly and unambiguously derivable, since it combines the particular choice of a particular buffer system (components (B) and (C)) with the particular choice of a particular pH range and the particular choice of component (A).

5. *First to third and fifth to seventh auxiliary requests; Article 123(2) EPC*

The considerations and conclusions under point 4 above apply *mutatis mutandis* to each of claims 1 of all these auxiliary requests, because the particular choice of the three components (A), (B) and (C) together with a particular pH range is contained in each of them, such combination being in breach of Article 123(2) EPC.

In claims 1 of the second and third auxiliary requests the lower limit of the pH range is taken from example 5, which constitutes an additional ambiguity in the attempt to derive the teaching of the claim from the original application.

6. *Eighth auxiliary request; Article 123(2) EPC*

The particular values for the concentration of the components (A), (B) and (C) in the eighth auxiliary request are based on example 2 on page 25 of the application as originally filed. However, this example 2 relates to "an **aqueous** antimicrobial **lock solution**" to be "applied between the sessions and removed before the next treatment" (see page 25 of the original description, lines 17 to 19; emphasis by the board) which is not generalisable to the subject-matter of claim 1 of this request, namely "a **pharmaceutical composition** for inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device" with the three components being present in whatever form in whatever solvent in or near whatever prosthetic device; which even includes a solution or dispersion of the components with a pH value suitable

for coating the prosthetic device before inserting it in a patient.

Moreover, the word "approximately" with regard to 3.3 grams/liter of citric acid, which is present in example 2, is now lacking in the claim and, despite the fixed value of 3.3 grams/liter, according to the claim "said citric acid is to be added to adjust the pH range to 4.75 to 5.25". Obviously, citric acid can only be used to adjust a pH if there is any variation possible in the content, and at least the word "approximately" is necessary to allow for any adjustment using citric acid.

Therefore, claim 1 of the eighth auxiliary request relates to an unallowable generalisation and modification of example 2 which contravenes the requirements of Article 123(2) EPC.

7. In these circumstances, the further arguments of the respondent cannot succeed either.

In view of claims 1 of the main request and the first to third and fifth to seventh auxiliary requests the respondent argues that the "or" on top of page 21 of the application as originally filed with respect to the content of acid or its salt was clearly to be read as an "and" because the indicated ranges of pH could not be reached by acid or salt alone.

On the other hand, on page 21, lines 18 to 19 of the original description it is stated "It is more preferred **that the acid be citric acid** and most preferred that it be used in combination with a citrate salt, e. g.,

sodium citrate, …", in addition "The foregoing anticoagulants can be used **alone in the free acid state**, but …" (ibid, page 22, lines 12 to 14) and "**The acid** and/**or** salt will be used in a concentration …" (ibid, page 22, line 18). All these statements in the description as originally filed emphasise the option to use an acid alone. Thus, the skilled person cannot derive directly and unambiguously from such disclosure that in all cases a buffer system must be used.

8. Thus, the subject-matter of the main request is in breach of Article 100(c) EPC and the first to third and fifth to eighth auxiliary requests do not meet the requirements of Article 123(2) EPC.

9. *Eleventh auxiliary request; Article 123(2) EPC*

9.1 The single claim of this request is to be derived from page 10, lines 11 to 20 together with page 25, lines 16 to 20 of the application as originally filed.

The claim relates to a composition as an aqueous antimicrobial lock solution, consequently a product per se, accompanied by features relating to its use and features relating to its physical or chemical characteristics. The features relating to the use of the compositions merely characterise the suitability of the composition for the indicated use.

9.2 In contrast to the claims as originally filed, which refer to methods and devices, compositions as a product per se are addressed under the heading "Summary of the invention" on page 9 of the description. The features characterising these compositions are to be derived

from the passage mentioning them (page 10, lines 11 and 12) followed by particular features characterising the components and others characterising the conditions of their use, altogether described in the form of a method on page 10, lines 13 to 20. In this context the conditions of their use represent the features characterising the compositions in the sense that they must be suitable for this use.

9.3 In the application as originally filed, the only example of a particular composition representing the features set out under the general description on page 10 mentioned above is example 2 on page 25. Examples 1 and 5 are directed to general, orientative tests of taurolidine/citric acid/citrate solutions under simplified conditions, example 3 relates to comparative compositions and example 4 is according to line 5 on page 27 of the application as filed "a more detailed description of the trial of example 2".

The decisive passage characterising the claimed composition is on page 25, lines 16 to 20. The particular medical details of the experiment, as far as the composition is concerned, are as such not relevant for the generalisation of its teaching.

The subject-matter of the single claim of the eleventh auxiliary request with all its features is to be derived from this passage, which has to be read together with the disclosure on page 10, lines 13 to 20.

9.3.1 The addition "at least" characterising 13.3 g/l as a lower limit of taurolidine content in the composition is directly derivable from the content of the

description of the application as filed (see example 2 together with page 16, line 13 to page 17, line 15) and can be accepted in the light of the common general knowledge of the skilled person who knows that the suitability for causing an antimicrobial effect is not bound to exactly one specific concentration of a microbiocide but more of it, as far as is known to be medically acceptable and does not cause problems relating to solubility, also has an antimicrobial effect. In a similar way it is acceptable that the claimed composition is not to be restricted in relation to its suitability according to an antimicrobial lock "applied between the sessions and removed before the next treatment" (see page 25 of the original description, line 17); in particular with respect to the active substances taurolidine and taurultam, the skilled person knows the circumstances to be taken into account in cases where the composition is not intended to be removed before the next treatment but for instance swept into the circulation of the patient.

9.3.2 The characterisation from page 10 of the original description, lines 19 and 20, "whereby there are no systemic anticlotting and no systemic biocidal effects" does not mandatorily have to appear in the claim, because on the basis of the effects described in the examples it can be accepted that this characterisation is automatically fulfilled when using a composition according to example 2.

9.3.3 The formulation with respect to the adjustment of the pH value at the end of the claim "wherein said citric acid is added to adjust the pH range to 4.75 to 5.25" was contained in the eighth and eleventh auxiliary

requests as filed in the written proceedings and in the description relating to example 2. Its amendment resulting in the new text "wherein said citric acid is added to adjust the pH **of the composition to the** range **of** 4.75 to 5.25" is occasioned by an objection of the board.

Various passages in the application as originally filed express the meaning of this finally amended (revised) claim of the eleventh auxiliary request, i.e. page 21, lines 3 and 4 as well as page 22, line 18 to page 23, line 7. Moreover, it is clear to the skilled person that addition of an acid cannot adjust a pH range but only the pH value of a composition.

Based on these passages in the description as originally filed, the same wording and meaning is represented in claim 1 as granted.

9.4 Under these circumstances, the provisions of Article 123(2) EPC are met by the subject-matter of the eleventh auxiliary request in its revised version.

9.5 The scope of the claim being narrowed with respect to product claim 1 as granted, the provisions of Article 123(3) EPC are also fulfilled.

10. *Remittal*

Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered at two instances, it is well recognised that any party may be given an opportunity for two readings of the important elements of a case.

The opposition division decided on the maintenance of the patent as granted, i.e. under the restrictions that Article 84 EPC, being no ground of opposition, and grounds of opposition contained in Article 100 EPC but not put forward by the opponent were not to be assessed.

Since, in contrast to this situation, auxiliary request 11 (revised version) is derived from the application as originally filed and the protection conferred is not extended, on this basis all further formal and substantive aspects of the EPC are to be assessed.

For this reason, auxiliary request 11 is to be regarded as a fresh case. A new situation is created with respect to the new claim, which should now be examined on its own merit.

Therefore, the board exercises its discretion under Article 111 EPC and remits the case to the first instance for further prosecution.

Order

For these reasons it is decided that:

1. The appeal is admissible.

2. The document entitled "Handelsregister des Kantons Zürich" filed with the appellant's letter dated 27 November 2012 is admitted into the proceedings.

3. The objection under Rule 106 and Article 112a EPC is rejected.

4. The decision under appeal is set aside and the case is remitted to the department of first instance for further prosecution on the basis of auxiliary request 11 (revised version), filed at the oral proceedings on 28 November 2012.

The Registrar: The Chairman:

N. Maslin M.C. Ortega Plaza