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# Datasheet for the decision of 2 October 2013

**Case Number:** T 0602/11 - 3.3.06

**Application Number:** 02800919.9

**Publication Number:** 1438379

**IPC:** C11D 3/39, A61L 2/20, A61L 2/16

**Language of the proceedings:** EN

**Title of invention:**
Decontamination of surfaces contaminated with prion-infected material with oxidizing agent-based formulations

**Patent Proprietor:**
STERIS INC.

**Opponent:**
Alfred Kärcher GmbH & Co. KG

**Headword:**
Deactivation of prions/STERIS

**Relevant legal provisions:**
EPC Art. 56, 108
EPC R. 99(2)
RPBA Art. 12(2)

**Keyword:**
"Appeal admissibile (yes)"
"Inventive step (no)" - all claim requests - obvious solution"

**Decisions cited:**
T 0432/88, T 1239/06, T 1384/06, T 0349/09

**Catchword:**
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 0602/11 - 3.3.06

# D E C I S I O N
**of the Technical Board of Appeal 3.3.06**
**of 2 October 2013**

| | |
|---|---|
| **Appellant:** (Opponent) | Alfred Kärcher GmbH & Co. KG<br>Alfred-Kärcher-Strasse 28-40<br>D-71364 Winnenden (DE) |
| **Representative:** | Hoeger, Stellrecht & Partner Patentanwälte<br>Uhlandstrasse 14c<br>D-70182 Stuttgart (DE) |
| **Respondent:** (Patent Proprietor) | STERIS INC.<br>43425 Business Park Drive<br>Temecula, CA 92590 (US) |
| **Representative:** | von Kreisler Selting Werner<br>Deichmannhaus am Dom<br>Bahnhofsvorplatz 1<br>D-50667 Köln (DE) |
| **Decision under appeal:** | **Decision of the Opposition Division of the European Patent Office posted 30 December 2010 rejecting the opposition filed against European patent No. 1438379 pursuant to Article 101(2) EPC.** |

**Composition of the Board:**

**Chairman:** B. Czech
**Members:** G. Santavicca
J. Geschwind

## Summary of Facts and Submissions

I. The appeal lies from the decision of the Opposition Division rejecting the opposition against European patent N° 1 438 379.

II. Claim 1 as granted reads as follows:

"*1. A method of deactivating prions characterized by: pretreating surfaces that carry prion infected material with an alkaline cleaner that attacks prions; and treating the surfaces with an oxidizing agent in one of liquid and gaseous form, the oxidizing agent including peracetic acid*".

III. The patent had been opposed in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC 1973) as well as of insufficiency of the disclosure (Article 100(b) EPC 1973).

The evidence considered in the opposition proceedings includes the following prior art document:

D1: K. Antloga et al, "*Prion Disease and Medical Devices*", ASAIO J. 2000, vol.46, no.6, pages S69 to S72

IV. In the decision under appeal, it was *inter alia* held

(a) that the priority date of 5 October 2001 was validly claimed;

(b) that the information given in the patent in suit was sufficient for carrying out the claimed method.

(c) that the claimed method was new since D1 did not unambiguously disclose a method comprising a

pretreating with an alkaline cleaner followed by treating with peracetic acid; and,

(d) that the claimed method was not obvious in the light of D1, taken as closest prior art, and the further prior art cited.

V. With its statement setting out the grounds of appeal, the appellant filed two new prior art documents. The appellant maintained *inter alia* its novelty objection based on the disclosure of D1 and still considered the claimed method to be obvious in the light of D1.

VI. In its response to the statement setting out the grounds of appeal, the patent proprietor/respondent *inter alia* challenged the admissibility of the appeal and maintained the auxiliary claim requests then on file. In said response, it also enclosed two new items of evidence.

VII. In response to a communication by the Board issued in preparation for the oral proceedings, the appellant *inter alia* submitted arguments in support of the admissibility of its appeal and regarding the alleged obviousness of the claimed method in the light of the cited prior art.

VIII. At the oral proceedings held on 2 October 2013, the respondent filed three sets of amended claims labelled first to third auxiliary requests. At the end of the oral proceedings, the decision was announced.

IX. Compared to Claim 1 as granted, Claim 1 of the first auxiliary request contains the additional features "*the cleaner having an alkalinity of at least 500 ppm*" and,

at the end of Claim 1, the additional functional indication "*to deactivate prions*".

Compared to Claim 1 according to the first auxiliary request, Claim 1 according to the second auxiliary request comprises the further feature "*in a concentration of a least 1000 ppm*" defining the concentration of the peracetic acid to be used.

Finally, compared to Claim 1 according to the second auxiliary request, Claim 1 according to the third auxiliary request comprises the further appended features "*wherein the cleaning and treating steps being carried out between 50 and 60°C*".

X. As relevant here, the arguments of the appellant can be summarised as follows:

*Admissibility of the appeal*

(a) Several passages of the statement setting out the grounds of appeal dealt with the decision under appeal. The fact that the statement setting out the grounds of appeal extensively detailed and concentrated on points already dealt with in the notice of opposition and the opposition submissions was at most a question of style, which could not lead to inadmissibility of the appeal. Finally, the decisions referred to by the respondents related to different situations and were not relevant to the present case.

*Main Request – Inventive step*

(b) The closest prior art was disclosed by D1, which not only generally dealt with prion decontamination and disinfection, and addressed the practices for sterilization of medical devices, but also reflected the background art known to the skilled person. In particular, D1 disclosed the decontamination of surgical instruments achieving a reduction of the prion load of 98% in one step and of 100% in two steps. The claimed method was distinguished therefrom by an alkaline pretreatment step.

(c) As regards the technical problem solved, it was not contested that some embodiments of the method according to the patent in suit might be considered as improved compared to the methods disclosed in D1. However, considering

(i) the breadth of Claim 1 (which neither required 100% efficacy nor any of the special features illustrated in the examples of the patent in suit to attain a very good performance) (incidentally, Formulations A and B of Example 4 were many times more alkaline than those mentioned in D1), and,

(ii) the absence of any evidence that the claimed method attained an improvement over D1 across the whole breadth of Claim 1,

the problem actually solved across the whole breadth of Claim 1 was merely the provision of an alternative method.

(d) D1 did not mention an alkaline pretreatment step preceding the application of peracetic acid. However, D1 disclosed that it was a daily clinical practice to clean the objects to be decontaminated, e.g. by an alkaline pretreatment, which was as such acknowledged *inter alia* in D1. In this respect, D1 mentioned a treatment carried out at room temperature with a 1 N NaOH solution. Therefore, the inclusion of such a pretreatment step in the method of D1 was an obvious measure for the skilled person and led to the claimed method.

*Auxiliary Requests - Inventive step*

(e) None of the new features introduced in the auxiliary requests, namely the alkalinity of at least 500 ppm, the deactivation of prions, the concentration of peracetic acid and the temperature range for first and second steps, required a change of the closest prior art (still D1) or of the problem solved. In fact, D1 disclosed that a 1 N NaOH solution was used to clean the objects to be decontaminated because such a solution also attacked prions; the peracetic acid used in D1 had a concentration of 1000 ppm; the decontamination step illustrated by D1 was carried out at a temperature of about 50°C. Using a higher temperature in the first step, e.g. to carry out both steps at the same temperature, or to shorten the cycle, or because the higher the temperature, the better the cleaning, was an obvious measure. Therefore, the conclusion drawn

for the main request also applied to all auxiliary requests.

XI. As relevant here, the arguments of the respondent can be summarised as follows:

*Admissibility of the appeal*

(a) Apart from an additional passage dealing with the question of priority, the passages dealing with the two newly filed prior art documents and the request to set aside the decision under appeal, the appellant had simply repeated the grounds of opposition as initially submitted, without providing any substantive argument against nor any link to the decision under appeal. Since the statement setting out the grounds of appeal did not set out clearly and concisely the reasons why the decision under appeal should be reversed or amended, it was inadmissible, as decided in e.g. T 1239/06 of 30 July 2008, T 432/88 of 15 June 1989, T 1384/06 of 26 June 2007 and T 349/09 of 26 February 2010.

*Main Request - Inventive step*

(b) D1 described the closest prior art. However, D1 merely disclosed potential strategies against prions.

(c) The method described by D1 was not efficient, in fact it had to be repeated to attain better efficacy. The examples of the patent in suit instead provided some evidence of an improvement.

For instance, when comparing the results of Example 4 with those of Example 2 (in both of which 2500 mg/l peracetic acid were used), it was apparent that the presence of an alkaline pretreatment step (Example 4) permitted to attain a model prion reduction ($log_{10}$) of less than 1 (i.e. a value lying between 1 and 10), which was better than the value 1 (i.e. 10) obtained in Example 2. In this respect reference was also made to Figure 5 and Table 6 of the patent in suit. As regards Formulations A and B of Example 4 of the patent in suit, they were used diluted, so that their alkalinity was that of a 0.5 to 1 N alkaline solution. Therefore, the problem solved was the provision of an improved method for decontamination of prion proteins.

(d) Many options for decontamination of prions were described in D1, such as the use of a strong alkali solution. This option, however, was not applicable to all of the devices, i.e. was not the right choice. The other documents invoked were all less relevant than D1. Therefore, even if the problem solved were the provision of an alternative method, the claimed method was not obvious over D1.

*Auxiliary Requests - Inventive step*

(e) Claim 1 according to each of the auxiliary requests contained further essential steps, in order to restrict the scope of Claim 1 and to specify more precisely the conditions leading to an improved decontamination. Considering that the

use of high temperature was contrary to the prior art, which disclosed that clumping of prions might occur, that the alkalinity was less than that disclosed by D1, that the improvement shown for 2500 mg/l peracetic acid in Example 4 of the patent in suit also applied to lower concentrations, such as 1000 mg/l, the claimed method was still superior to that of D1, and non-obvious.

XII. The appellant (opponent) requested that the decision under appeal be set aside and that the European patent No. 1 438 379 be revoked.

XIII. The respondent (patent proprietor) requested that the appeal be rejected as inadmissible (main request) or be dismissed (first auxiliary request), or, alternatively that the patent be maintained on the basis of the claims according to one of the first to third auxiliary requests filed at the oral proceedings.

## Reasons for the Decision

*Admissibility of the appeal*

1. The respondent did not contest (neither in writing nor at the oral proceedings) that the extent to which the decision was to be amended was clear at least from the notice of appeal, i.e. from the request to set aside the decision and revoke the patent.

The objection raised by the respondent concerns the question whether the statement setting out the grounds

of appeal contains sufficient indications concerning the reasons for setting aside the decision impugned, the extent to which it was to be amended as well as the facts and evidence on which the appeal was based (Rule 99(2) EPC and Article 12(2) of the Rules of Procedure of the Boards of Appeal or RPBA). In particular this objection raises the question whether the statement setting out the grounds of appeal contains arguments against and links to the decision under appeal.

1.1 The statement setting out the grounds of appeal details several issues specifically addressed in the decision under appeal, *inter alia:*

(a) the construction of Claim 1;

(b) invalidity of the first claimed priority of 5 October 2001;

(c) sufficiency of the disclosure;

(d) lack of novelty over D1, when read on the basis of the knowledge deriving from other cited documents;

(e) lack of an inventive step having regard to D1.

Hence, it cannot be considered that the statement setting out the grounds of appeal merely refers to the contents of the notice of opposition or of submissions in opposition proceedings.

1.2 As regards the objection that the appellant simply repeated, almost verbatim, the grounds and arguments submitted during the opposition proceedings, the Board notes that:

(a) The arguments provided in the statement setting out the grounds of appeal in respect of the

validity of the first priority claim include, in addition to the material submitted with the letter of 25 August 2010 (which is not the notice of opposition), further arguments (last two paragraphs on page 7 and first two paragraphs on page 8), which *inter alia* address a conclusion (concerning priority) made in the decision under appeal (Point 3, first paragraph, last sentence, of the reasons thereof).

(b) Also, as regards the alleged insufficiency of the disclosure (page 9, penultimate paragraph), the appellant questioned why the decision under appeal (point 4, last paragraph, of the reasons thereof) acknowledged that some items of information were missing but then decided that they were not relevant for the sufficiency.

(c) Furthermore, as regards novelty over D1, the statement setting out the grounds of appeal (Point 5) contains almost four pages of new arguments (from page 13, last sentence of the second paragraph, to page 16), in which, *inter alia*, reference (page 16, second paragraph) is again made to the decision under appeal (Point 5, second paragraph, thereof), to contest the conclusion that the opponent, rather than the patent proprietor, had the onus to prove the composition of the product Steris® 20 disclosed in D1.

1.3 It follows from the foregoing that the statement setting out the grounds of the present appeal neither merely refers to the submissions made before the

opposition division nor is a verbatim repetition of the grounds and arguments submitted during the opposition proceedings, as alleged by the respondent. Instead, at least from some passages (e.g. last two paragraphs on page 7, first paragraph on page 8, penultimate paragraph of page 9 and page 16, second paragraph), it can be inferred why the appellant contests the decision under appeal.

1.4 The decisions referred to by the respondent to support its line of argument concerned cases differing substantially in term of the particular underlying circumstances. For the following reasons, the findings in these decisions have no bearing on the questions to be answered in the present case:

(a) T 349/09 of 26 February 2010 (Point 4 of the reasons, last two sentences) relates to a case where the statement setting out the grounds of appeal was held to be a "copy and paste" version of the notice of opposition, lacking any verbatim or explicit link to the decision under appeal. Also, this decision concerned an appeal against an interlocutory decision that the patent could be maintained in amended form, not against a decision to reject the opposition as in the present case (acknowledged in said decision as being a different case; see point 19 of the reasons). In the present case, however, the Board finds that for the reasons given in Point 1.2, *supra*, the statement of grounds is not (only) a "copy and paste" version of submissions produced in the opposition proceedings and contains links, albeit few, to the decision under appeal.

(b) In decision T 1239/06 of 30 July 2008 (Point 1.1 of the reasons) the content of the statement setting out the grounds of appeal was not an issue. The decision concerns a case where the response to the statement setting out the grounds of appeal was considered to be unsubstantiated because it referred only in general to writs submitted before the first instance. A comparison was made with cases where (as e.g. in T 349/09 mentioned *supra*) statements of grounds merely referring generally to submissions made in the first instance proceedings were considered insufficient.

(c) Such was also the situation in the case underlying decision T 432/88 of 15 June 1989 (Point 2 of the reasons): Since the statement of grounds only made a general reference to the submissions in the foregoing opposition proceedings, the appeal against the rejection of the opposition was rejected as inadmissible.

In the present case, however, as pointed out in Point 1.2, *supra*, the statement of grounds does not merely refer generally to submissions made during the opposition proceedings.

(d) In decision T 1384/06 of 26 June 2007 the admissibility of the appeal does not appear to have been an issue.

1.5 Considering the particular circumstances of the present case (points 1.1-1.3, *supra*), the Board need not deal with the question whether or not the submission of two

new prior art documents with the statement setting out the grounds of appeal and the relevant arguments provided in support thereof contribute to making the present appeal admissible.

1.6 Therefore, the appeal is admissible (Article 108 and Rule 99(2) EPC).

*Main Request*

2. Novelty

At the oral proceedings, novelty was no longer in dispute. The board sees no reason for reversing the finding of the opposition division concerning novelty over D1. Distinguishing features of the claimed subject-matter become apparent from the analysis of the closest prior art D1 (point 3.2.4, *infra*).

3. Inventive step

3.1 The invention

The invention relates to prion deactivation (paragraph [0001]) and concerns the decontamination of surfaces contaminated with prion-infected material with oxidizing agent-based formulations (title and claim 1).

3.2 Closest prior art

3.2.1 For the board, the closest prior art document is D1, which also discloses methods for prion deactivation of surfaces contaminated with prion-infected material and aims at overcoming (page S70, left column, last four

sentences) the same drawbacks as the patent in suit. Moreover, like the patent in suit, D1 proposes (page S70, right column, "Efficacy of Peracetic Acid") the use of an oxidizing agent-based formulation, namely diluted peracetic acid, as inactivating agent.

At the oral proceedings, it was also common ground between both parties that D1 was the most appropriate starting point for the assessment of inventive step.

3.2.2 D1 is a scientific article relating to prion diseases and medical devices (title). In particular, D1 illustrates tests of the efficacy of a peracetic acid based liquid chemical sterilant (Steris® 20 of the Steris Corporation, Mentor OH), the latter being an oxidizing agent-based formulation in the sense of Claim 1 of the patent in suit. The sterilant is prepared in a use dilution for the reprocessing of medical devices at 50-56°C (page S70, right column, last paragraph, last sentence).

More particularly, D1 (S71, left column, last paragraph, first two sentences) illustrates the decontamination of stainless steel surgical blades (hence, of "*surfaces*", in the sense of Claim 1 of the patent in suit) which had been contaminated by directly cutting through Creutzfeldt-Jacob disease (CJD) brain tissue to provide a protein concentrate of about 5 mg brain tissue/blade. The contaminated blades were exposed to the Steris 20 sterilant (at 1000 mg/l peracetic acid (PAA)) respectively for one and two consecutive 12 minutes exposures at 50°C. Figure 3 of D1 and its corresponding description (page S71, right column, first two paragraphs) show that the level of resistant prion

protein ($PrP^{res}$) was notably reduced, e.g. on average 98.4% (range 96.5 to 99.6%) after a single sterilant treatment of the blades. After the second exposure to the sterilant, no detectable $PrP^{res}$ was found. From this result, the authors of D1 conclude that PAA based sterilant may be an effective agent for the decontamination of prion contaminated medical instruments.

3.2.3 Thus D1 discloses (in terms of the features of Claim 1 as granted) "*a method of deactivating prions*" on "*surfaces that carry prion infected material*" (i.e. surfaces of medical instruments) including the step of "*treating the surfaces with an oxidizing agent in ... liquid ... form, the oxidizing agent including peracetic acid*".

3.2.4 D1 also mentions alkaline pretreatments in the contexts of previously used methods for the decontamination and sterilisation of medical instruments (page S70, sections entitled "Decontamination and Sterilization" and "Medical Device Transmission"). However, a method comprising both an alkaline pre-treatment and a subsequent PAA treatment is not disclosed, as correctly found in the decision under appeal (point 5 of the reasons).

3.3 Technical problem according to the respondent

At the oral proceedings, the respondent submitted that in the light of the closest prior art D1, the technical problem consisted in the provision of an **improved** method for the decontamination of surfaces infected with prions.

3.4 Solution

According to the appellant this problem is solved by the method of deactivating prions according to claim 1, which is characterized by "***pre-treating*** *surfaces that carry prion infected material* ***with an alkaline cleaner that attacks prions***" before "*treating these surfaces with an oxidizing agent in one of liquid and gaseous form, the oxidising agent including peracetic acid*" (emphasis added).

3.5 Alleged success of the claimed solution

3.5.1 As regards the alleged improvement over the method disclosed in D1, the board observes the following:

(a) None of the examples of the patent in suit reflects the closest prior art D1. In particular, Example 4, the sole example illustrating a method according to claim 1 at issue, merely contains a comparison with alkaline cleaner formulations, but no comparison with peracetic acid-containing formulations. No further comparative data were submitted in the course of the examination, opposition and appeal proceedings.

(b) A comparison of Example 4 (including a pretreatment step and a desinfection step with 2500 mg/l peracetic acid solution) of the patent in suit with Example 2 of the patent in suit (comprising only a treatment with a sterilant solution containing 2500 mg/l), shows the following: As apparent from Figure 5 of the patent in suit, the method of

Example 2 results in a $\log_{10}$ prion model reduction from 6 to 1 (i.e. from 1 million to 10 units) in about 12 minutes, whereas the method of Example 4 (irrespective of the alkaline cleaner formulation used) results (according to Table 6 of the patent in suit) in a $\log_{10}$ reduction of the same IFDO prion model of less than 1 (i.e. to less than 10 units).

Said comparison thus shows that under certain operating conditions an alkaline pretreatment step may indeed lead to a better decontamination.

(c) However, some of the particular operating conditions used in Example 2 are not reflected in Claim 1. The latter encompasses treatments at comparatively low temperatures (i.e. at less than 50 C), in the absence of surfactants and at peracetic acid concentration of less than 1000 mg/l. According to D1, treatments at room temperature are less effective (S70, right column, last paragraph, first sentence). However, concentrations lower than 2500 ppm PAA have not been shown to lead to an improvement (see Figure 5 of the patent in suit).

3.6 Hence, the board does not accept that the data comprised in the patent in suit make it plausible, let alone demonstrate, that compared to the method of D1 (treatment with peracetic acid containing sterilant), an improvement attributable to the features of the claimed method is achieved across the whole breadth of Claim 1 at issue.

3.7 Reformulation of the technical problem

Since, for the above reasons, a formulation of the technical problem effectively solved in terms an improvement over the closest prior art D1 cannot be accepted, the technical problem must be redefined in a less ambitious manner, and can be seen in the provision of a further method of deactivating prions present on contaminated surfaces.

3.8 Obviousness

3.8.1 It remains to be decided whether for the skilled person starting from the closest prior art D1, using common general knowledge and trying to solve the stated technical problem, the inclusion of a step of "*pretreating surfaces that carry prion infected material with an alkaline cleaner that attacks prions*" into the method disclosed by D1 was obvious in the light of D1 alone or of a combination of D1 with other prior art relied upon by the appellant.

3.8.2 D1 (S70, left column, last paragraph) acknowledges previously applied routine methods of decontamination and sterilization and, in respect of the medical device transmission (S70, right column, first paragraph), reviews clinical practices which are expressly recommended when handling suspected cases of prion disease (S70, right column, second paragraph).

3.8.3 As regards the routine methods of decontamination, D1 discloses that recommended methods for disinfection and sterilization of medical devices include a **pre**treatment (emphasis added) with sodium hydroxide and prolonged

steam sterilization (S70, left column, last paragraph, 5th sentence). Also, in two further instances (S70, right column, first paragraph, second and fourth sentences), D1 describes known **two-step** methods respectively as follows: "1 hour sodium hydroxide soak with subsequent steam sterilization (134°C, 1 hour)" and "soaked for 1 hour in 2 N NaOH (or 2 hours in 1 N sodium hydroxide), rinsed with water, and autoclaved at 134°C (gravity displacement steam autoclaving for 1 hour; porous load steam autoclaving for one 18 minute cycle at 30 lbs/psi or six 3-minute cycles at 30 lbs/psi)".

Hence, D1 acknowledges that a two-step method for prion deactivation including an alkaline pre-treatment was known.

3.8.4 Moreover, among the clinical practices for preventing medical device transmission which are recommended when handling suspected cases of prion disease, D1 also mentions in particular "washing surfaces with 1N NaOH and leaving as a wet film for 1 hour at room temperature" (S70, right column, second paragraph, last sentence). Hence, D1 also acknowledges the known fact that an alkaline treatment based on sodium hydroxide attacks the prions.

3.9 When deciding whether any motivation for modification of the method using peracetic acid as taught by the experimental part of D1 is given to the skilled person by the known use of pretreating devices to be sterilised with e.g. an alkaline cleaner, also taught in D1, the objective that the skilled person sets out to attain must be taken into account.

3.10 Since in the present case the objective is the mere provision of a further method of deactivating prions on contaminated surfaces, the known option of a pretreatment with alkaline cleaners that attack prions is at hand for the skilled person reading D1, who would thus obviously consider following this recommended clinical practice.

3.11 Therefore, the method according to claim 1 as granted does not involve an inventive step (Article 52(1) and 56 EPC.

3.12 Consequently, the main request of the appellant is not allowable.

*First to Third Auxiliary Request*

4. Admissibility of the requests

4.1 At the oral proceedings, the respondent re-filed copies of three sets of amended claims that had already been filed as first to third auxiliary requests during the opposition proceedings, and which auxiliary requests the respondent had upheld in its reply to the statement setting out the grounds of appeal. No objection to this course of action was raised by the appellant.

4.2 The requests filed at the oral proceedings were thus admitted into the proceedings despite their late filing (Article 13(3) RPBA).

5. Amendments

5.1 Compared to Claim 1 as granted, the respective Claims 1 according to each of the first to third auxiliary requests contain additional features mentioned in Point IX, *supra*, namely:

(a) "*the cleaner having an alkalinity of at least 500 ppm*" and "*to deactivate prions*" (all auxiliary claim requests);

(b) "*in a concentration of a least 1000 ppm*" (second and third auxiliary requests); and,

(c) "*wherein the cleaning and treating steps being carried out between 50 and 60°C*" (third auxiliary request).

5.2 Since the subject-matter of amended claims 1 according to all three auxiliary requests fails on the ground of lack of an inventive step (*infra*), the question whether the sets of claims according to said auxiliary requests meet the requirements of Articles 123(2) and (3) and 84 EPC need not be dealt with.

6. Inventive step

6.1 Claim 1 according to the third auxiliary request contains all of the additional limiting features of the respective claim 1 according to auxiliary requests 1 and 2, i.e. is the narrowest. For the sake of conciseness, having regard to the negative finding on inventive step for all the auxiliary claim requests, the subject-matter defined by Claim 1 according to the third auxiliary request is thus dealt with first.

6.2 The closest prior art is undisputedly still described by D1.

6.3 For the board, the experimental data contained in the patent in suit are not sufficient to demonstrate that adoption of the measures now additionally required by claim 1 (i.e. the features listed under point 5.1 a) to c) leads to a better decontamination under all sets of conditions encompassed by claim 1. As a case in point, no improvement over D1 has been shown for a method carried out at 50°C in both steps but at a concentration of 1000 ppm PAA only, without surfactant and at an alkali level of 500 ppm only.

Hence, the technical problem solved remains the one considered for Claim 1 of the main request (point 3.7, *supra*), i.e. the provision of a further method of deactivating prions present on contaminated surfaces.

6.4 D1 in particular discloses that:

(a) the alkaline cleaner may be a 1 N solution of sodium hydroxide, thus a strong solution having a concentration of 40 g/l of sodium hydroxide (i.e. 40 000 mg/l or ppm as compared to the lower limit of 500 ppm incorporated into the claims 1). Irrespective of whether the alkali concentration ("*alkalinity of at least 500 ppm*") defined in claim 1 is to be understood as molar (see e.g. "molarity of KOH" mentioned in the patent in suit, paragraph [0038], second sentence) or as $Na_2O$ (as alleged by the respondent in its response to the statement setting out the grounds of appeal on page 6, lines 1-13), the alkaline cleaner disclosed

by D1 has an alkalinity substantially greater than 500 ppm.

(b) Peracetic acid deactivates prions (S71, right column, first paragraph, second to fourth sentences).

(c) The peracetic acid solution used in the experimental part of D1 for the decontamination of the stainless steel surgical blades has a concentration of 1000 mg/l (S71, left column, last paragraph, third sentence).

(d) The cleaning step may be carried out at room temperature (S70, right column, second full paragraph, last sentence) whereas the treating step is carried out at temperatures of 50-56°C (S70, right column, last line), in particular 50°C (S71, left column, last paragraph, third sentence).

(e) Although D1 does not disclose an alkaline pretreatment carried out between 50 and 60°C, it has neither been argued nor proven by evidence, nor is it plausible either, that this measure would provide an unexpected better decontamination. Indeed, it is generally known that cleaning at higher than room temperature at least requires less time to be carried out (e.g. shorter cleaning cycle), and usually is also more effective with respect to cleaning. Considering that the sterilant used in the method of D1 *inter alia* includes surfactants to prevent aggregation of prions (S70, right column, last paragraph, second to last

sentence), the skilled person would not be deterred from doing so.

6.5 Since also these further measures were at hand for the skilled person, the method defined by Claim 1 of the third auxiliary request was obvious over D1.

6.6 Thus, the subject-matter of Claim 1 of auxiliary request 3 does not involve an inventive step (Articles 52(1) and 56 EPC).

6.7 Consequently, auxiliary request 3 is not allowable.

6.8 Considering that the respective claims 1 according to auxiliary requests 1 and 2 are broader in scope and encompass the obvious method according to claim 1 according to auxiliary request 3, the former, by implication, likewise fail on the ground of lack of an inventive step (Articles 52(1) and 56 EPC).

6.9 Auxiliary requests 1 and 2 are thus not allowable either.

7. It follows from the foregoing that none of the auxiliary claim requests complies with the EPC.

**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:

K. Boelicke B. Czech