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D E C I S I O N
of 16 March 2006

Case Number: T 1018/03 - 3.3.10

Application Number: 94903267.6

Publication Number: 0668784

IPC: A61L 2/20

Language of the proceedings: EN

Title of invention:

A method of enhanced penetration of low vapor pressure
chemical vapor sterilants during sterilization

Patentee:

American Sterilization Company

Opponent:

Johnson & Johnson Medical, Inc.

Headword:

-

Relevant legal provisions:

EPC Art. 52(1), 54, 56, 83, 84, 111(2), 123(2) and (3)

Keyword:

"Decision re appeal - res judicata"

"Amendments (allowable) - res judicata"

"Clarity (yes) - objected expression already present in the
claims as granted"

"Sufficiency of disclosure (yes) - res judicata"

"Novelty (yes) - res judicata"

"Inventive step (yes)"

Decisions cited:

T 0301/87, T 0027/94, T 0993/98

Catchword:

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Case Number: T 1018/03 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 16 March 2006

Appellant: American Sterilizer Company
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 4 July 2003
revoking European patent No. 0668784 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: R. Freimuth
Members: P. Gryczka
P. Schmitz

Summary of Facts and Submissions

- I. The mention of the grant of European patent 0 668 784, in respect of European patent application No. 94903267.6, which is based on the International application PCT/US93/11079 filed on 11 November 1993, was published on 28 August 1996.
- II. A notice of opposition was filed in which revocation of the patent in its entirety was requested on the grounds of lack of novelty and inventive step, insufficiency of disclosure and added subject-matter (Article 100(a), (b) and (c) EPC).

The following documents were cited during the opposition proceedings:

- (1) EP-A-0 302 420,
- (2) US-A-4 643 876 and
- (3) US-A-4 348 357.
- III. By a decision posted on 28 July 1998 the European patent was revoked pursuant to Article 102(1) EPC. In its decision the Opposition Division ruled that the subject-matter of claim 1 as granted lacked novelty in view of citation (1).
- IV. The Proprietor of the patent in suit lodged an appeal against that first decision of the Opposition Division. The Board in charge of that appeal held in decision T 993/98 (not published in OJ EPO) that the invention underlying the opposed patent was sufficiently

disclosed. The subject-matter of claim 1 of the then pending main and first auxiliary request lacked novelty over the process disclosed in document (1) whereas claim 1 of the then pending second and third auxiliary request contravened the requirements of Article 123(2) EPC. The Board held that the amended claims of the then pending fourth auxiliary request complied with the requirements of Articles 84 and 123(2) and (3) EPC and that their subject-matter was novel over the disclosure of documents (1) and (2). Since the Opposition Division had not considered the issue of inventive step the Board remitted the case to the first instance for further prosecution.

Claim 1 of the then pending fourth auxiliary request read as follows:

"1. A method of enhancing penetration of low vapor pressure sterilant vapors during sterilization of an article in an enclosed chamber comprising the consecutive steps of:

- (a) evacuating said chamber to a pre-determined pressure below atmospheric pressure;
- (b) introducing sterilant vapors into said chamber and, consequently, raising the pressure in said chamber to a second pre-determined pressure below atmospheric pressure in a pre-determined time;
- (c) allowing said sterilant vapors to be distributed throughout said chamber for a pre-determined time period;
- (d) introducing a gas into said chamber within a third pre-determined time period, and raising the pressure within said chamber to a third pre-determined

pressure up to atmospheric pressure to compress the vapor sterilant; and

(e) allowing said gas and said sterilant vapors to remain in said chamber for a pre-determined sterilant exposure time period;

wherein

(f) steps (a) - (e) are repeated between 2 and 32 times to obtain a predetermined level of sterilization."

V. After remittal of the case by the Board, the Opposition Division revoked the patent-in-suit pursuant to Article 102(1) EPC. In its decision issued in writing on 4 July 2003, the Opposition Division held that amended claim 1 of the then pending main and first auxiliary request did not comply with the requirements of Article 123(2) EPC. The amended claims of the then pending auxiliary requests 2 to 8 complied with the requirements of Articles 84 and 123 EPC. Their subject-matter was novel but lacked inventive step.

VI. On 9 September 2003, the Appellant (Proprietor of the patent in suit) lodged an appeal against the above decision. During the oral proceedings held before the Board on 16 March 2006 the Appellant submitted a fresh set of six claims as main and sole request superseding any previous request.

Claim 1 of said request reads as follows:

"1. A method of enhancing penetration of low vapor pressure sterilant vapors during sterilization of an article **having closed or open ended lumens** in an enclosed chamber comprising the consecutive steps of:

- (a) evacuating said chamber to a first pre-determined pressure **in a range from between 0,133 mbar (0.1 Torr) and 13,3 mbar (10 Torr)**;
- (b) introducing sterilant vapors into said chamber and, consequently, raising the pressure in said chamber to a second pre-determined pressure **in a range from between 7,98 mbar (6 Torr) and 79,8 mbar (60 Torr)** in a pre-determined time;
- (c) allowing said sterilant vapors to be distributed throughout said chamber for a pre-determined time period **which is less than or equal to twice the half-life of said sterilant vapor within the enclosed chamber**;
- (d) introducing a gas into said chamber within a third pre-determined time period **between 3 to 120 seconds**, and raising the pressure within said chamber to a third pre-determined **sub-atmospheric pressure which is greater than six times the second pre-determined pressure** to compress the vapor sterilant; and
- (e) allowing said gas and said sterilant vapors to remain in said chamber for a pre-determined sterilant exposure time period **which is greater than the half-life of said sterilant while inside said chamber**;
- wherein
- (f) steps (a) - (e) are repeated between 2 and 32 times to obtain a predetermined level of sterilization."
(**emphasis** added by the Board; the sections in bold type identify the differences of present claim 1 to claim 1 of the then fourth auxiliary request underlying the decision T 993/98 (see point IV above)).

VII. The Appellant submitted that the amendments in claim 1 of the main and sole request were supported by the application as filed. Claim 1 was restricted to a

method which was applied to articles having closed or open ended lumens. Since the process according to claim 1 of the then fourth auxiliary request underlying the previous decision T 993/98 was considered to be novel, the process according to the more restricted present claim 1 was also novel. With regard to inventive step, document (1) represented the closest prior art. The problem solved by the claimed process was the provision of an efficient process for sterilising complex articles with narrow openings. The prior art documents did not suggest to apply vapor compression pulses to the sterilant vapor by introducing a gas into the evacuated chamber in order to push the sterilant into regions which are difficult to sterilise, to start the significant part of the sterilisation process after reaching a specific sub-atmospheric pressure and to take that pressure as the starting point for the next sterilisation cycle. These process steps cooperated in a synergistic way by improving the sterilisation efficiency and the energy and time consumption. Moreover, none of the cited references dealt with the problem of sterilising articles having a shape which was difficult to expose to the sterilising medium. For these complex articles it was important, for obtaining a sufficient concentration of active sterilant in the entire article, that the time periods of exposure to the sterilant were defined in function of the half-life of the sterilant. The prior art documents were silent on that point. Thus, the claimed process involved an inventive step.

VIII. The Respondent (Opponent) submitted that present claim 1 contravened the requirements of Article 123(2) EPC, since the application as filed disclosed a method

applied to a material with closed or open ended lumens only in combination with technical features which have been omitted in claim 1. The feature "half-life of said sterilant" introduced in claim 1 was not clear. Although it was not contested that the invention was sufficiently disclosed and that the claimed process was novel, no inventive step could be acknowledged when considering the process disclosed in document (1) as the closest prior art. The wording of claim 1 did not restrict the claimed method to the treatment of a material with closed or open ended lumens. In any case, document (1) also concerned the problem of penetration of the sterilant into a complex article since it disclosed the sterilisation of a paper disc which was sealed in a "Tyvek" package. Starting from this prior art, the problem to be solved by the invention underlying the patent-in-suit could be defined as to improve the efficiency of the sterilisation method in order to provide a complete sterilisation. However, the examples in the patent specification showed that this problem was not solved since a complete sterilisation was not always achieved. The solution provided by the claimed process was only characterized by repeating the sterilisation cycles between 2 and 32 times and by introducing the gas in step (d) within a time period between 3 to 120 seconds, since the other features specified in claim 1, in particular the time periods defined in steps (c) and (e), were explicitly or implicitly disclosed in document (1). It was a matter of routine to repeat the sterilisation cycle if a single sterilisation cycle did not provide satisfactory results. No effect was shown for repeating the process between 2 and 32 times, nor was any effect linked to the feature defining the time period of 3 to 120

seconds for introducing the gas into the chamber so as to raise the pressure and create a pressure pulse. Furthermore, the use of pressure pulses for enhancing the penetration of the sterilant in complex objects was known from document (3). Thus, it was obvious to the skilled person to apply the features distinguishing the claimed process from the closest prior art in order to solve the technical problem underlying the patent-in-suit. Therefore, the claimed process did not involve the required inventive activity.

- IX. The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request submitted during the oral proceedings before the Board.

The Respondent requested that the appeal be dismissed and withdrew during the oral proceedings its request for an apportionment of costs submitted in writing.

- X. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.
2. *Binding effect of the previous decision T 993/98 of Board 3.3.2*

In line with the established jurisprudence of the Boards of Appeal the binding effect of a decision of a board provided for in Article 111(2) EPC extends not

only to the first instance department to which the case was remitted, but also to the Board in charge of the case in a subsequent appeal proceedings (T 27/94 not published in OJ EPO, point 2 of the reasons; Case Law of the Boards of Appeal of the EPO, 4th edition 2001, VII.D.10.1).

Since the binding effect applies only in so far as the facts are the same it has to be determined to which extent the facts in the present case remain the same and what has been concluded in the previous decision T 993/98 with respect to those same facts.

2.1 The following issues were definitely decided in the previous decision T 993/98 (point IV, *supra*):

- (a) The requirements of Article 83 EPC were met and Article 100(b) EPC did not prejudice the maintenance of the patent on the basis of claim 1 of any of the then pending requests (point 3 of the Reasons for the Decision);
- (b) The amended claims of the then pending fourth auxiliary request were allowable as being adequately supported by the disclosure of the application as filed, thus complying with the requirements of Articles 84, and 123(2) and (3) EPC (point 8 of the Reasons for the Decision);
- (c) Novelty of the subject-matter claimed in the then pending fourth auxiliary request was acknowledged (points 8.1 to 8.3 of the Reasons for the Decision);

(d) The amended feature in step (d) of claim 1 "*a third pre-determined sub-atmospheric pressure*" was allowable within the terms of Rule 57(a) and Article 123(2) EPC (points 5.1 and 5.2 of the Reasons for the Decision);

(e) In the assessment of novelty the decision concluded on and established the features disclosed in document (1) (point 5.4 of the Reasons for the Decision).

These conclusions finally settled by the previous Board are *res judicata* and the present Board is bound by them when examining the issues raised in the present appeal proceedings in so far as the same facts are concerned (Article 111(2) EPC).

2.2 Present claim 1 incorporates all the technical features of claim 1 of the then fourth auxiliary request underlying the previous decision T 993/98. In addition, further features have been introduced in the present claim in order to overcome inventive step objections raised during the present appeal proceedings. Therefore, the present request does not contravene any conclusion drawn in the decision T 993/98 and thus, is in conformity with the *ratio decidendi* of said decision (Article 111(2) EPC).

3. *Amendments*

3.1 *Admissibility*

The Appellant submitted the present set of claims during the oral proceedings before the Board, claim 1

thereof comprising numerous amendments vis-à-vis claim 1 of the then fourth auxiliary request underlying decision T 993/98. However, all those amendments, except one, have already been present in a claim on which the decision under appeal is based. The only new feature introduced into claim 1 at the oral proceedings before the Board consists in defining the article to have closed or open ended lumens. This amendment was prompted by objections raised at the oral proceedings in the discussion of inventive step as to the breadth of the claim. Therefore, this amendment, though filed late in the proceedings, was at that time appropriate and necessary with the consequence that the Board, when exercising its discretion, sees no pertinent reason to reject present claim 1 on that score.

3.2 *Article 123(2) and (3) EPC.*

The amendments in claim 1 of the then fourth auxiliary request underlying decision T 993/98 have been found in said decision to be in conformity with the requirements of Article 123(2) and (3) EPC (*res judicata*, point 2.1 (b) above). Present claim 1, in addition, is restricted to a method applied to an article having closed or open ended lumens. This modification is based on page 14, lines 14 and 15 and page 15, lines 20 and 21 of the application as filed. The Respondent argued that the material was only defined in combination with specific features defining the method of sterilisation. However, in the above passages of the application as filed the article is defined without any feature defining the method of sterilisation going beyond those defined in present claim 1. This amendment is, thus, allowable.

The pressure ranges specified in step (a), i.e. from between 0,133 mbar (0.1 Torr) and 13,3 mbar (10 Torr), and in step (b), i.e. from between 7,98 mbar (6 Torr) and 79,8 mbar (60 Torr), are based on claims 3 and 5 of the application as filed, respectively.

The time period defined in step (c), i.e. which is less than or equal to twice the half-life of said sterilant vapor within the enclosed chamber, is based on claim 6 of the application as filed.

The time period defined in step (d), i.e. between 3 to 120 seconds, is based on claim 7 of the application as filed.

That the third pre-determined pressure in step (d) is greater than six times the second pre-determined pressure is based on claim 8 of the application as filed.

The time period defined in step (e), i.e. which is greater than the half-life of said sterilant while inside said chamber, is based on claim 10 of the application as filed.

Consequently, the amended claim 1 fulfils the requirements of Article 123(2) EPC.

The dependent claims 2 to 6 are based on dependent claims 4, 12, 13, 14 and 15 of the patent as granted, respectively, and it has never been contested that these dependent claims were adequately supported by the application as filed (Article 123(2) EPC).

When compared to the patent as granted, the amendments made to claim 1 amount to a restriction of the claimed subject-matter with the consequence that it does not extend the protection conferred by the patent as granted.

Consequently, the amended claims fulfil the requirements of Article 123(3) EPC.

3.3 *Clarity (Article 84 EPC).*

The Respondent objected to the clarity of the feature "half-life of said sterilant" introduced into claim 1. However, this feature was already present in claims 6 and 10 of the patent as granted and its introduction into claim 1 does not generate any unclarity.

Consequently, the clarity of that feature cannot be objected to since lack of clarity is not a ground for opposition (see decision T 301/87, OJ EPO 1990, 335, point 3.8 of the Reasons).

4. *Sufficiency of disclosure*

The Respondent did not object to the sufficiency of disclosure in relation to present claim 1 in the present appeal proceedings.

It was decided in the previous decision T 993/98 that the invention was sufficiently disclosed when considering the then pending fourth auxiliary requests (*res judicata*, point 2.1 (a) above) which embraces the present request.

Consequently, the ground for opposition under Article 100(b) EPC is disqualified.

5. *Novelty*

The Respondent did not raise any objection with regard to the novelty of the subject-matter of claim 1. Since the method according to claim 1 of the then fourth auxiliary request underlying decision T 993/98 was found to be novel (*res judicata*, point 2.1 (c) above), the even more restricted subject-matter of present claim 1 is necessarily also novel (Article 52(1) and 54 EPC).

6. *Inventive step*

6.1 The Appellant and the Respondent considered that document (1) represented the closest prior art document for the assessment of inventive step in accordance with the "problem-solution approach". The Board sees no reason to depart from this findings.

6.1.1 The previous decision T 993/98 found in point 5.4 of the reasons for the decision numerous features comprised in present claim 1 to be disclosed in document (1). These conclusions are, thus, *res judicata* in the present appeal proceedings (see point 2.1 (e) above) with the consequence that they are final and no longer open to any challenge from the Appellant or Respondent.

Document (1) discloses a method of sterilising an article with hydrogen peroxide vapour at very low

vapour pressures in a vacuum chamber (page 2, lines 8 to 10; page 3, lines 16 to 27; *res judicata*).

Document (1) addresses the sterilisation of objects such as medical instruments (see page 2, lines 9 and 10). Since medical instruments cover objects having a complex form in the sense of the patent in suit, in the Board's judgement, that document, though not describing that form specifically, also embraces the sterilisation of complex articles.

After the article has been placed in the vacuum chamber (process step (1), page 4, line 39), the sterilisation cycle disclosed in example II involves the following consecutive steps:

(A) evacuating the chamber to a pressure of 0.13 mbar (page 5, lines 52 to 53; *res judicata*); this step corresponds to step (a) of the method according to present claim 1;

(B) introducing and vaporizing hydrogen peroxide to produce in the chamber a vapour concentration of 1.0 mg H₂O₂/litre; this inevitably causes the sub-atmospheric pressure in the chamber to rise slightly, as confirmed by the first part of the sentence at lines 24 to 25 on page 5 (*res judicata*). In addition, document (1) discloses that at this stage the pressure is maintained in the chamber below 30 torr (page 4, lines 43 to 45); this step corresponds to step (b) of the method according to present claim 1;

(C) allowing H₂O₂ vapour to diffuse throughout the chamber for a pre-determined period of 2 minutes (see page 5, line 57; *res judicata*);

(D) introducing filtered air into the vacuum chamber to increase the pressure in the system to a desired (pre-determined) level of sub-atmospheric pressure (page 5, lines 56 to 57 and "Final Pressure" in table II on page 6; *res judicata*). In addition, the final pressure indicated in table II on page 6 is greater than 6 times the initial pressure in any experiment;

(E) exposing the article to be sterilised to the H₂O₂ vapour for a pre-determined period of 20 minutes (*res judicata*). Neither party to the proceedings contested that the period of 20 minutes is greater than the half-life of the sterilant while inside the chamber so that this step corresponds to step (e) of the method according to present claim 1.

6.1.2 The Respondent alleged that the time period of 2 minutes disclosed in the method of document (1) (example II, page 5, line 56) corresponded to a time period which was less than or equal to twice the half-life of said sterilant vapor within the enclosed chamber, as required in step (c) of the process of claim 1. This finding was contested by the Appellant.

The half-life of the sterilant varies with the nature of the enclosed chamber and the article to be sterilised since the half-life corresponds to the time required for the sterilant concentration to be reduced by half either due to decomposition or adsorption (patent specification, page 7, lines 20 to 23). Thus,

it is not possible without determining the half-life of the sterilant under the experimental conditions of example II of document (1), to establish whether or not the time period of 2 minutes complies with the required threshold, i.e. less than or equal to twice the half-life of the sterilant. The Respondent, who carries the onus of proof for its allegation, did not rely on any experimental evidence in this respect.

Thus, in the absence of any substantiating facts and corroborating evidence, the Respondent's arguments are mere speculations which cannot convince the Board.

Therefore, it cannot be concluded that in the process disclosed in document (1) the sterilant vapors are allowed to be distributed throughout said chamber for a pre-determined time period which is less than or equal to twice the half-life of said sterilant vapor within the enclosed chamber.

- 6.2 Having regard to this prior art, the Appellant submitted that, in conformity with the specification of the patent in suit, the objective technical problem underlying the subject-matter as defined in claim 1 was to provide a further method for sterilising effectively complex articles (patent specification, page 6, lines 34, 35, 40 and 41).

The Respondent formulated a more ambitious problem underlying the patent in suit, namely to improve the sterilisation process so as to achieve complete killing of microorganisms, but argued at the same time that this problem was not solved by the claimed method. However the Opponent, here Respondent, cannot formulate

a more ambitious problem than the problem which according to the Proprietor, here Appellant, underlies the patent in suit and simultaneously object to the fact that this more ambitious problem was not effectively solved. This line of argumentation of the Respondent is, thus, to be disregarded and the problem remains as defined by the Appellant.

- 6.3 The solution to this problem proposed by the patent in suit is the method according to claim 1, which is characterized in that the time period for allowing the sterilant vapors to be distributed throughout the chamber for a pre-determined time period is less than or equal to twice the half-life of said sterilant vapor within the enclosed chamber (step (c)); the time period for introducing a gas into said chamber is between 3 to 120 seconds (step (d)); and the steps (a) - (e) as defined in claim 1 are repeated between 2 and 32 times and that the article to be sterilised has closed or open ended lumens.

The presence of lumens in the article to be sterilised is a mandatory feature of the subject-matter of amended claim 1. That article is enclosed in a chamber and "said chamber", i.e. including the article, is subjected to the consecutive steps, starting with step (a). Therefore, the Respondent's argument that the chamber might be empty or that the article may not have lumens is not supported by the facts.

- 6.4 The calculations reported in the specification of the patent in suit reveal that when applying the claimed method, the kill potential for microorganisms at the inlet and the outlet of a tube to be sterilised are

nearly identical, meaning that the sterilisation time at the dead end of the tube is nearly equal to the sterilisation time at the inlet of the tube (page 7, line 36 to page 8, line 36). According to examples 2 and 5, sterilisation within a closed end lumen is achieved by using the claimed method. With respect to example 5 the Respondent argued by referring to the sterilisation data at a penetration depth of 120 cm into the lumen that the sterilisation was not totally complete. However, since the technical problem underlying the invention is not defined to achieve **complete** sterilisation, this objection is not pertinent.

Thus, the Board is satisfied that the technical problem underlying the patent in suit as defined herein above (point 6.3) has been successfully solved.

- 6.5 It remains to be decided whether or not the proposed solution to that objective technical problem, namely the method according to claim 1, is obvious in view of the state of the art.
- 6.5.1 Based on the findings that the sporicidal activity of hydrogen peroxide is enhanced at very low pressure (page 3, lines 22 and 23), the process of sterilisation disclosed in document (1) requires that the sterilisation is carried out at low pressure (claim 1, steps (b) and (d)). However, document (1) does not address the specific problems linked to the sterilisation of complex articles with narrow openings and apertures, in particular the difficulty of providing sufficient active sterilant within the whole article. Since document (1) does not address this problem, it cannot give any hint to its solution.

The examples of document (1) which relate to the sterilisation of paper disks enclosed in a "Tyvek" package (page 5, lines 5 and 6), do not deal with any problem of penetration and distribution of the sterilant due to the complexity of an article having narrow openings and apertures, since the "Tyvek" package is a disc.

Thus, document (1) on its own, cannot render the method as defined in claim 1 obvious.

6.5.2 Document (2) discloses a method for sterilising articles in gaseous plasmas (column 1, lines 6 and 7). The process is based on the findings that an initial contact of the material to be sterilised with hydrogen peroxide before the generation of plasma decreases the total time and power required to accomplish sterilisation (column 2, line 63 to column 3, line 2; claim 1). In this process hydrogen peroxide acts as a precursor of the reactive species (column 3, lines 18 and 19), since after the contact of the article to be sterilised with hydrogen peroxide, a plasma must be generated by applying RF energy (column 5, line 45 to column 6, line 8).

Therefore, document (2) on its own or in combination with document (1) cannot point to the claimed solution in which the generation of plasma is not required and hydrogen peroxide *per se* acts as sterilant.

6.5.3 As does the patent-in-suit, document (3) relates to the sterilisation of articles with irregular shapes and having long narrow apertures (column 1, lines 9 and 10).

However, document (3) discloses for that purpose a method of sterilisation implying plasma species and, consequently, already for this reason cannot point to the claimed solution in which the sterilant is hydrogen peroxide *per se* and not plasma species generated therefrom (claim 1; column 2, lines 6 to 10). In addition, document (3) explicitly teaches that the use of chemicals requires long sterilisation times and suffers from problems of toxicity and limited shelf life (column 1, lines 28 to 32), so that the skilled person is rather discouraged from using a chemical such as hydrogen peroxide to sterilise complex articles. Nor does document (3) give any pointer to the solution proposed by the patent in suit, in particular to link the time period for allowing the sterilant vapors to be distributed throughout the enclosed chamber with the half-life of the sterilant, let alone that this step is followed by introducing a gas within the specific time period of between 3 to 120 seconds, when lumens are to be sterilised.

The Respondent argued that document (3) taught the use of pressure pulses while sterilising complex articles and thus rendered the claimed solution, which relied on the same principle, obvious for a skilled person. However, document (1) already discloses pressure pulses (see point 6.1.1 (D) above). Thus, whether or not pressure pulses are taught in document (3) is irrelevant in the assessment of obviousness since the solution proposed by the patent in suit is not characterised by this feature when starting from document (1) (see point 6.3 above). Furthermore, since the plasma species are generated outside the article to be sterilised in the process disclosed in document (3),

the pressure pulses are used to introduce the active species into the article (column 4, lines 44 to 46). This step does not correspond to step (d) of the claimed process where the active species, i.e. the hydrogen peroxyde vapors, are already present in the article when introducing the gas for raising the pressure. In addition, the claimed process does not imply a sequence of pressure pulses as illustrated by figure (2) of document (3), but requires the repetition of the steps (a) to (e) and thus an evacuation of the chamber before reintroducing the sterilant and the gas.

For these reasons, document (3) on its own or in combination with document (1), does not point to the claimed solution of the technical problem defined herein above.

6.6 Therefore, the method according to claim 1 of the main and sole request, and for the same reason, that according to the dependant claims 2 to 6, involve an inventive step within the meaning of Articles 52(1) and 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of claims 1 to 6 of the main request submitted during the oral proceedings before the Board and a description yet to be adapted.

The Registrar:

The Chairman:

C. Moser

R. Freimuth