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D E C I S I O N
of 26 June 2002

Case Number: T 0993/98 - 3.3.2

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 STERILIZER COMPANY

Opponent:
Johnson & Johnson Medical, Inc.

Headword:
Sterilization/AMERICAN STERILIZER COMPANY

Relevant legal provisions:
EPC Art. 54, 83, 100(a)(b)(c), 111(1), 112(1), 123(2)(3)
EPC R. 57a, 66(1)

Keyword:
"Main and first auxiliary requests: amendments acceptable under Article 123(2)(3) and Rule 57a; novelty (no)"
"Second and third auxiliary requests: amendments contravene Article 123(2) EPC.
"Fourth auxiliary request: amendments acceptable under Article 123(2)(3) and Rule 57a; novelty (yes)"
"Remittal to the first instance"
"Question of law: remittal to the Enlarged Board of Appeal (no) - prerequisites not fulfilled"

Decisions cited:
T 0004/83, T 0198/84, T 0124/87, T 0182/89, T 0666/89

Catchword:
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Case Number: T 0993/98 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 26 June 2002

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 28 July 1998 revoking European patent No. 0 668 784 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: P. A. M. Lançon
Members: G. F. E. Rampold

Summary of Facts and Submissions

I. European patent No. 0 668 784 ("the patent") was granted with 15 claims in response to European patent application No. 94 903 267.6. Claim 1 as granted read as follows:

"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 pre-determined pressure up to atmospheric pressure; and
(e) allowing said gas and said sterilant vapors to remain in said chamber for a pre-determined time period;
(f) repeating steps (a)-(e) as needed to obtain a pre-determined level of sterilization."

Dependent claims 2 to 15 related to elaborations of the method according to claim 1.

II. The respondent filed notice of opposition seeking

revocation in full of the European patent under Article 100(a) EPC for alleged lack of novelty and inventive step, under Article 100(b) EPC because of alleged insufficiency of disclosure and under Article 100(c) EPC on the ground of added subject-matter. In support of these grounds, the respondent presented, *inter alia*, the following citations:

(1) EP-A-0 302 420

(2) US-A-4 643 876

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 notice of opposition met all legal requirements of the EPC and therefore rejected the patentee's objections against the admissibility of the opposition as unfounded. The opposition division also noted that it could not recognise in the patent as granted an alleged violation of Article 123(2) EPC which could have formed the basis for the respondent’s opposition under Article 100(c) EPC. Similarly, it saw in the respondent's submissions insufficient substantiation for an objection under Article 83 EPC to alleged insufficiency of disclosure and accordingly no adequate basis for opposition under Article 100(b) EPC. The opposition division found that citation (1) disclosed all technical features of claim 1 as granted and revoked the attacked patent for lack of novelty.

IV. An appeal was lodged against the decision of the opposition division. The appellant (patentee) presented together with the statement setting out the grounds of appeal three revised sets of claims forming its main,

first and second auxiliary requests.

V. The board issued a communication accompanying a summons to oral proceedings. In this communication, it was questioned whether the proposed limitation of the pressure range specified in step (d) of the claimed process by replacing the originally disclosed feature "up to atmospheric pressure" with "sub-atmospheric pressure" was adequately supported by the disclosure in the application as filed. Further, the respondent's attention was drawn to the fact that the notice of opposition contained nothing that could be regarded as an indication of the facts, evidence and arguments in support of the ground for opposition referred to in Article 100(c) EPC. Since the first instance did not recognise in the patent a violation of Article 123(2) EPC in the decision under appeal and since, moreover, the opposition under Article 100(c) EPC was to be considered non-existent *ab initio* and therefore inadmissible, the respondent was informed that the question of allowability of any amendments effected to the claims before grant did not arise as such under Article 123(2) EPC in the present case. The respondent was also informed that, in the rapporteur's provisional view, the first instance was correct in deciding that the patent met the requirements of Article 83 EPC.

VI. With a letter dated 24 May 2002, the appellant submitted new first, second, third, fourth and fifth auxiliary requests to replace all previously filed auxiliary requests.

(á) Steps (a) and (d) in claim 1 of the main request differ from steps (a) and (d) in claim 1 as granted as follows:

"(a) evacuating said chamber to a *first* pre-determined pressure below atmospheric pressure;

(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 *sub-atmospheric pressure;*"

(â) Steps (a), (d) and (e) in claim 1 of the first auxiliary request differ from the corresponding steps in claim 1 as granted as follows:

"(a) evacuating said chamber to a *first* pre-determined pressure below atmospheric pressure;

(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;"

(ã) Steps (a) and (d) to (f) in claim 1 of the second auxiliary request differ from the corresponding steps in claim 1 as granted as follows, with step (g) being added:

"(a) evacuating said chamber to a *first* pre-

determined pressure below atmospheric pressure;

(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;

(f) *repeating step (a); wherein*

(g) steps (b)-(e) are repeated as needed to obtain a pre-determined level of sterilization;"

(ä) Steps (a) and (d) to (f) in claim 1 of the third auxiliary request differ from the corresponding steps in claim 1 as granted as follows, with step (g) being added:

"(a) evacuating said chamber to a *first* pre-determined pressure below atmospheric pressure;

(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, wherein the pressure differential between the third and second pressures is greater than the pressure differential between the second and first pressures;

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

(f) *repeating step (a); wherein*

(g) steps (b)-(e) are repeated as needed to obtain a pre-determined level of sterilization;"

(å) Steps (a) and (d) to (f) in claim 1 of the fourth auxiliary request differ from the corresponding steps in claim 1 as granted as follows:

"(a) evacuating said chamber to a *first* pre-determined pressure below atmospheric pressure;

(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 pre-determined level of sterilization."

VII. Under cover of a faxed letter dated 24 June 2002, the appellant filed eight new sets of claims forming its auxiliary requests 6 to 13.

VIII. Oral proceedings were held on 26 June 2002. The respondent maintained alleged insufficiency of disclosure (Article 100(b) EPC) as a ground for opposition, but it did not present any comments on this ground during the hearing. As a result of the board's views as expressed early on during the oral proceedings, the appellant waived its objection as to alleged inadmissibility of the respondent's opposition and withdrew its request for reimbursement of the appeal fee. During the hearing the appellant presented the following question of law and suggested its referral to the Enlarged Board of Appeal in the event that the board should be inclined to consider the content of citation (1) as relevant to the assessment of the novelty of the claimed subject-matter in the patent:

"If a claim in a prior art document contains a teaching including a plurality of steps wherein a specific process step, however, is not mentioned for solving the problem, which process step, however, is disclosed only in connection with a description of tests aiming at adjusting test parameters so as to make the tests comparable with each other, is this prior art document novelty destroying for a proposal combining the features of claim 1 with said specific step ?"

IX. The appellant's arguments submitted in the statement of grounds of appeal and in oral proceedings can, in essence, be summarised as follows:
The amended claims in all of the appellant's requests presently on file were not only sufficiently clear and concise but also adequately supported by the originally filed documents and complied in these formal respects with the requirements of Articles 84 and 123(2) EPC. The requirements of Article 123(3) EPC were likewise met.

The claimed process in the patent differed in several respects from the sterilization process disclosed in (1), as far as process step (d) in claim 1 of all requests was concerned. The process as disclosed in Examples I and II of citation (1) did not include anything like step (d) of the claimed process comprising introducing a pressure gas into the vacuum chamber and raising the pressure to a pre-determined sub-atmospheric or atmospheric level to compress the vapour sterilant. Step (d) was in the claimed process in the patent a separate procedural step which followed process step (c) wherein the sterilant vapour was allowed to distribute itself throughout the chamber and in the dead end lumen. Instead, in the process of (1) a small amount of air was, only if necessary, admitted into the chamber during the period when the aqueous solution of hydrogen peroxide injected into the chamber was allowed to vaporise and to create a hydrogen peroxide atmosphere in the chamber.

The disclosure in lines 55 to 56 on page 4 of (1) related to the step of feeding a sterile gas or filtered, bacteria free air into the chamber to raise the pressure in the chamber to atmospheric levels and

to permit the sterilised articles to be removed. This final step in the process of (1), which was specifically cited by the opposition division against the novelty of the claimed process, produced pressure equalisation upon completion of the sterilization cycle to allow removal of the sterilized articles from the enclosed chamber. This final step as such was not comparable at all with step (d) of the claimed process which served to compress the vapour sterilant, as sterilization occurs, and to drive the sterilant vapour further into the article than the sterilant vapour would naturally diffuse.

In the process of (2) the chamber was evacuated to a pressure of approximately 0.05 Torr. Then an aqueous solution of hydrogen peroxide was injected. No information was provided in (2) about the pressure control during the entire period of about 5 to 30 minutes before the plasma was generated. Steps (d) to (f) of the claimed process in claim 1 of the patent were simply not disclosed in the cited document and citation (2) was thus far from being prejudicial to the novelty of the claimed subject-matter in the patent.

X. The respondent’s arguments submitted in writing and orally at the hearing can be summarised as follows:

Claim 1 of the main request had been amended to require the pressure in the enclosed chamber to be raised to a third predetermined sub-atmospheric pressure after the gas had been introduced in step (d). Although the description and drawings of the application as filed might only refer to sub-atmospheric pressure levels being reached on introduction of the pressure gas, this was no justification for distorting the ordinary

meaning of the requirement in original claim 1 for the pressure of step (d) "to be up to atmospheric pressure". There was no complicated terminology in this expression and therefore no complicated interpretation of it was needed. Thus, the original wording of step (d) of claim 1 did not provide clear and unambiguous support for the "sub-atmospheric requirement" in step (d) of claim 1 of the main request. Even if one were to accept that the examples and the description in Figure 1 of the application as filed referred to sub-atmospheric pressure, there would be no general statement in the application as filed that the pressure gas raised the chamber pressure to a sub-atmospheric level. To base the "sub-atmospheric pressure" requirement in claim 1 of the main request on the specific sub-atmospheric pressures given in the application as filed would result in an inadmissible intermediate generalisation.

Claim 1 in the first auxiliary request contained in both steps (d) and (e) amendments which were not allowable in view of Rule 57a EPC.

Claim 1 of the second and third auxiliary requests covered the case where evacuation step (a) was repeated without steps (b) to (e) being repeated. In the application as filed each instance of a repeat of the evacuation step (a) was followed by each one of steps (b) to (e) of claim 1. Thus, claim 1 in the second and third auxiliary requests was without foundation in the originally filed documents.

Irrespective of the added-matter issue, claim 1 of all requests lacked novelty over (1) and (2). Citation (1) made known a method of sterilizing an article with

hydrogen peroxide vapour in a vacuum chamber. After the chamber had been evacuated to a sub-atmospheric pressure and hydrogen peroxide vapour had been introduced therein, this inevitably caused the sub-atmospheric pressure in the chamber to rise slightly. The hydrogen peroxide vapour was allowed to diffuse throughout the chamber. Filtered air was then introduced into the vacuum chamber to raise the pressure to a new sub-atmospheric level. Thus (1) made available all of the steps positively required by claim 1 of the main request.

Citation (2) disclosed a method of sterilizing in an enclosed chamber an article with hydrogen peroxide vapour as the precursor for the active species generated during the plasma generation cycle by electrical discharges. The general sterilization procedure was described from column 5, line 45 to column 6, line 7, of citation (2). Step (2) of citation (2) was equivalent to lines 1 and 2 of claim 1. Consecutive steps (2) to (6) in citation (2) were equivalent to steps (a) to (e) of claim 1. When a plasma was generated in step (5) of citation (2), the temperature and pressure were raised and more liquid was vaporised, thus introducing more gas into the chamber. Thus, step (5) in citation (2) corresponded to step (d) in the claimed process and the general disclosure in citation (2) deprived claim 1 of novelty. Example VII of citation (2) disclosed a two-cycle sterilization procedure and anticipated thus not only steps (a) to (e) but also step (f) of claim 1 in the main, first and fourth auxiliary requests.

XI. The appellant requested that the decision under appeal be set aside and that the patent be maintained in

amended form either on the basis of the set of claims in the main request filed on 7 December 1998 together with the statement of the grounds of appeal or on the basis of the set of claims in one of the auxiliary requests 1 to 5, all filed on 24 May 2002, or in one of the auxiliary requests 6 to 13, all filed on 24 June 2002.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Since the respondent did not contest the board's finding that the substantiation of the ground for opposition recited in Article 100(c) EPC was insufficient to admit this ground into the proceedings, it is not necessary to go into further detail on this point.

3. The description of the patent includes six worked examples the feasibility of which was not challenged by the respondent. Accordingly, there can be no doubt that the patent describes in detail more than one way of carrying out the invention. The respondent argued, however, in its reply to the statement of the grounds of appeal that the patent did not provide sufficient information to allow the skilled person to operate the claimed invention within the full scope of claim 1.

The burden of proof lies with the respondent (opponent) to show that there is insufficiency under Article 83 EPC (see decision T 182/89, OJ EPO 1991, 391). The

board finds that this burden of proof has not been discharged. In the board's judgment, the patent contains sufficient information and examples which include broadly varying parameters (see eg Examples 4 and 5) to allow the claimed invention to be reproduced by the skilled practitioner "without undue burden" within the full scope of claim 1. Since moreover, the respondent did not provide any convincing or objective evidence, let alone real proof, to show in an unequivocal manner that a skilled reader would be unable to carry out the claimed invention in any embodiment, the board concurs with the finding in the decision under appeal that the requirement of Article 83 EPC is met and that, consequently, Article 100(b) EPC does not prejudice the maintenance of the patent on the basis of claim 1 in any of the present requests.

4. As is apparent from paragraph VI above, the main request and all auxiliary requests have, *inter alia*, been amended so as to specify the pressure in step (a) of claim 1 as **first** pre-determined pressure and in step (d) as **third** pre-determined pressure. Whereas these amendments do not contravene Article 123(2) and (3) EPC, the question arises whether they are also acceptable under the terms of Rule 57a EPC. This Rule, which according to Rule 66(1) EPC also applies to the appeal proceedings, requires that the amendments are occasioned by grounds for opposition specified in Article 100 EPC. Whether or not the proposed amendments can be admitted into the appeal proceedings is to be decided by the board in the exercise of its discretion. The appellant argues that, in contrast to the claimed process in the patent, the sterilization process in (1) did not include three distinctly different levels of pressure and that the above-mentioned specification was

introduced to delimit the claimed process more clearly and precisely against the prior art of (1). The board follows this argument because the proposed amendments could, at least in principle, contribute to a potential delimitation of the claimed subject-matter against citation (1) which was cited in support of a ground of opposition. It should be borne in mind that this potential suitability is sufficient for an amendment to be allowable under Rule 57a EPC as a fair attempt to overcome a potential objection, irrespective of whether the attempt is successful or not. The above-mentioned amendments in claim 1 of all requests are therefore considered acceptable under Rule 57a EPC.

Main request

5. The main request amends claim 1 of the patent to require the pressure in the enclosed chamber to be raised to a third pre-determined sub-atmospheric pressure after the pressure gas has been introduced in step (d).

5.1 As a preliminary point it should be noted that, in the board's judgment, the skilled reader would give the expression *"..... up to atmospheric pressure....."*, as used in original claim 1 to define the upper limit to which the pressure can be raised in the chamber in step (d), nothing other than its ordinary meaning, namely raising the **pressure up to** and **including atmospheric pressure**. Accordingly, the board is unable to share the appellant’s view that this expression could possibly be construed as meaning sub-atmospheric pressure levels only.

5.2 Notwithstanding the above, the board considers that the

proposed limitation of the pressure in the enclosed chamber in step (d) to sub-atmospheric pressure is clearly implied by and therefore derived from the whole disclosure as such. As indicated in point 5.1 above, the expression *"..... up to atmospheric pressure....."* in original claim 1 already included **two** possible options, namely (i) sub-atmospheric pressure and (ii) atmospheric pressure. The proposed limitation of the pressure in step (d) of claim 1 to the originally already envisaged option (i) was occasioned by the objection in the decision under appeal against the novelty of original claim 1 and is adequately supported by the application as filed. Thus, the description, dependent claims and drawings of the application as filed refer without exception to sub-atmospheric pressure levels being reached on introduction of the pressure gas in step (d) (see page 15, lines 8 to 11; Example 1, lines 19 to 20; Example 4, lines 22 to 24, claim 9; Figure 1). The proposed amendment is therefore acceptable under the terms of Article 123(2) EPC and Rule 57a EPC.

5.3 Irrespective of the amendment in step (d) of claim 1 requiring the pressure in the enclosed chamber to be raised to a third pre-determined sub-atmospheric pressure, claim 1 lacks novelty over the prior art of citation (1).

5.4 Citation (1) discloses a method of sterilizing an article with hydrogen peroxide vapour at very low vapour pressures in a vacuum chamber (see page 2, lines 8 to 10; page 3, lines 16 to 27). The prior art of (1) therefore concerns a method of the type to which claim 1 of the patent is directed, hydrogen peroxide vapour used in (1) corresponding to the *"low vapor*

pressure sterilant vapors" called for by claim 1 (see also dependent claim 13).

After the article has been placed in the vacuum chamber (see citation (1), process step (1); page 4, line 39), the sterilization cycle disclosed in Example II of citation (1) involves the following consecutive steps (see page 5, line 50 onwards):

(A) evacuating the chamber to a pressure of 0.13 mbar (0.1 torr) (see page 5, lines 52 to 53) - corresponding step (a) in the process of claim 1 in the patent;

(B) introducing and vaporizing hydrogen peroxide to produce in the chamber a vapour concentration of 1.0 mg H_2O_2/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 - corresponding to step (b) in the process of claim 1 in the patent;

(C) allowing H_2O_2 vapour to diffuse throughout the chamber for a pre-determined period of 2 minutes (see page 5, line 57) - corresponding to step (c) in the process of claim 1 in the patent;

(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 (see page 5, lines 56 to 57) and "Final Pressure" in Table II on page 6) - corresponding to step (d) in the process of claim 1 in the patent;

(E) exposing the article to be sterilized to the H_2O_2 vapour for a pre-determined period of 20 minutes - corresponding to step (e) in the process of claim 1 in the patent;

Since step (f) in the process of claim 1 of the main request is purely optional, citation (1) makes available to the public a sterilization method including all of the consecutive steps positively required by claim 1 of the main request. Claim 1 therefore lacks novelty over the prior art of (1).

5.5 The appellant submitted at the hearing that the sterilization method of Example II in (1) comprising the consecutive procedural steps (A) to (E) did not illustrate the teaching of the claim, since claim 1 in (1) lacked the step of introducing air into the chamber. Instead, according to the appellant, the particular sterilization method of Example II was used in citation (1) for the sole purpose to test in a series of experiments the effect of actual sterilization pressure in step (D) on sporidical activity and to make these experiments comparable with each other. In so far as the appellant appeared to suggest in its submission during oral proceedings that the information provided in Example II of (1) has practically no meaning and only the teaching of the claim of citation (1) should be considered to determine what had been made available to the public, it had ignored the established jurisprudence of the boards of

appeal, according to which it is necessary to consider the whole content of a citation ("whole content approach") when deciding the question of novelty (see e.g. T 4/83, OJ EPO 1983, 498, especially Reasons, point 4; T 198/84, OJ EPO 1985, 209; T 124/87, OJ EPO 1989, 491, especially Reasons, point 3.2; T 666/89, OJ EPO 1993, 495, especially Reasons, points 5 and 6).

When examining for novelty, it should be taken into consideration that any information in a patent specification which conveys to the person skilled in the art a technical teaching belongs to the content of the disclosure irrespective of whether or not it falls within the scope of the claims or what purpose it serves. In applying this principle to the case in suit, it is essential that the specific teaching for technical action in step (D) of citation (1) and in step (d) of the process of claim 1 in the patent is **exactly the same**, namely introducing filtered air into the vacuum chamber and raising the pressure in the system to a desired (pre-determined) level of sub-atmospheric pressure. The particular purpose this teaching serves in either case is irrelevant to the assessment of novelty. For that reason the claimed process in claim 1 of the main request lacks novelty.

5.6 Under Article 112(1) EPC the board of appeal refers any question of law to the Enlarged Board of Appeal of its own motion or at the request of a party if it considers the Enlarged Board's decision necessary for deciding a particular case. In the present case, given the clear-cut situation explained in points 5.4 and 5.5 above, the board sees no need for a decision by the Enlarged Board of Appeal with regard to the question formulated by the appellant. Quite apart from that the general

prerequisites for a referral to the Enlarged Board of Appeal are not fulfilled in the present case, given that questions may only be referred to the Enlarged Board in order to ensure uniform application of the law or if an important point of law arises. Neither of these requirements is met in the present case since the law is applied within the framework of existing case law concerning the understanding of the average skilled person (see especially point 5.5 above). The deciding board is not departing from the case law laid down by a number of other boards nor is it deciding an important point of law whose resolution would be of general interest for the future. In the present case, the Board is merely applying proven principles of law to an individual case. There is therefore no question of referring the matter to the Enlarged Board of Appeal.

First auxiliary request

6. Claim 1 in the first auxiliary request contains the amendments referred to in point 3 above. Moreover, claim 1 differs from claim 1 in the application as filed and the patent as granted by including the particular purpose of introducing the pressure gas in step (d) *"to compress the vapor sterilant".* In addition, claim 1 specifies in step (e) that the pressure gas and the sterilant vapours are allowed to remain in said chamber for a pre-determined *"sterilant exposure"* time period. As regards the first amendment, this is taken from the disclosure in lines 25 to 26 on page 13 of the application as filed. As regards the amendment in step (e), this is based on the disclosure in lines 6 to 8 on page 14 stating that *"after an exposure time [to the vapor sterilant], a vacuum pull down follows the vapor compression .....".*

6.1 As indicated in point 6 above, the amendments to claim 1 in the first auxiliary request are, in the board's judgment, adequately supported by the originally filed documents and comply with the provisions of Article 123(2) and (3) EPC. Whilst the respondent accepted the support for the amendments in the application as filed, it objected to their insertion in claim 1 as being not allowable in view of Rule 57a EPC.

6.2 The board accepts the appellant's argument that both amendments were introduced to present an alternative for delimiting the claimed process in the patent against the prior art of (1), were the board to find the reference in the main request to a sub-atmospheric pressure not allowable, as indicated in the board's communication. The appellant also emphasised that the first instance erroneously based its objection as to lack of novelty on a comparison of step (d) of the claimed process with the final step of pressure equalisation upon completion of the sterilization cycle in citation (1). It consequently argued that the proposed amendments also served a better delimitation against the prior art of (1) to avoid the danger of such misinterpretation. The board accepts these arguments and exercises its discretion in favour of the appellant on the basis of its conclusive considerations in point 4 above. The above-mentioned amendments which have been introduced not only in the first auxiliary request but also in the second, third and fourth auxiliary requests are therefore considered acceptable under Rule 57a EPC.

6.3 The reasons which led to the rejection of the main request on the ground of lack of novelty apply equally

to the first auxiliary request. It is clear to a person skilled in the art that the technical feature of introducing air into the vacuum chamber to increase the pressure in the system in step (D) of Example II in (1) has the inevitable effect of compressing the hydrogen peroxide vapor sterilant. The indication of the purpose *"to compress the vapor sterilant"* in step (d) of claim 1 of the first auxiliary request therefore cannot confer novelty on a technical feature which is known *per se*.

Similarly, Step (E) in citation (1) which comprises exposing the article to be sterilized to the H_2O_2 vapour sterilant for a pre-determined period of 20 minutes anticipates the newly introduced feature in step (e) of the claimed process *"for a pre-determined sterilant exposure time period".*

6.4 In view of the above, the first auxiliary request cannot succeed.

Second and third auxiliary requests

7. Claim 1 in the second and third auxiliary requests contains the amendments referred to in point 4 and in point 6 above in respect of steps (d) and (e). Claim 1 also includes the added feature of "repeating step (a)", whereas in the following step (g) only *"steps (b) to (e) are repeated as needed to obtain a pre-determined level of sterilization"*. Accordingly, claim 1 covers the case where evacuation step (a) is repeated without steps (b) to (e) being repeated.

7.1 The appellant alleges that this amendment is based on the disclosure in the following passage on page 14,

lines 6 to 13:

- *"After an exposure time, a vacuum pulldown follows the vapor compression in order to remove the residual sterilant vapors and eliminate humidity in preparation for the next sterilization pulse;"*

and on the disclosure in the passage on page 19, lines 28 to 30:

- *"The chamber is then evacuated again to pressure P_1 and the procedure is repeated."* -

Neither of the cited passages in the description provides adequate support for the proposed amendment. As regards the first passage, this does not refer to the chamber being evacuated to a first pre-determined pressure below atmospheric pressure, as is required in step (a) of claim 1. As regards the second passage, this clearly teaches the skilled person that once evacuation step (a) has been carried out, the remaining steps (b) to (e) are repeated.

7.2 Moreover, Figure 1 shows that the evacuation step at the end of the pressure pulse is followed by a further injection of sterilant vapour, ie the commencement of a second pressure pulse.

7.3 To summarize, in the application as filed, there is no disclosure of carrying out the evacuation step (a) by itself without steps (b) to (e) being repeated. Thus, claim 1 in the second and third auxiliary requests contravenes the provisions of Article 123(2) EPC. It follows that the second and third auxiliary requests cannot succeed.

Fourth auxiliary request

8. Claim 1 in the fourth auxiliary request contains the amendments referred to in points 4 and 6 above in respect of claim 1 of the first auxiliary request. In addition, claim 1 of the fourth auxiliary request includes in step (f) the feature of dependent claim 11 in the application as filed and the patent as granted requiring that steps (a) to (e) be repeated between 2 and 32 times.

Dependent claims 2 to 12 correspond to dependent claims 2 to 10, 12 and 13 in the application as filed and the patent as granted and dependent claims 13 and 14 correspond to dependent claims 14 and 15 in the patent as granted. For the reasons given in paragraph V above concerning the allowability of amendments effected to the claims before grant, claims 14 and 15 of the patent as granted provide in the present case adequate support for the corresponding claims 13 and 14 in the fourth auxiliary request. The present version of the claims in the fourth auxiliary request is therefore acceptable as being adequately supported by the disclosure in the application as filed and complying in this formal respect with Articles 84 and 123(2) EPC.

In claim 1 as granted, the "repeat" requirement in step (f) was purely optional ("as needed"). Claim 1 as granted thus also covered the cases where steps (a) to (e) were carried out only once or were repeated only once or more than 32 times. As claim 1 as granted was thus no doubt broader than claim 1 in the fourth auxiliary request, the requirements of Article 123(3) EPC are likewise met.

8.1 The feature of repeating any or all of the individual steps (A) to (E) of the sterilization process described in citation (1), let alone the requirement of repeating said steps between 2 and 32 times, is nowhere disclosed in the cited document. Since the respondent did not contest that step (f) in claim 1 of the fourth auxiliary request confers novelty on the claimed process in the patent over the prior art of (1), it is not necessary to go into further detail on this point.

8.2 The prior art of the US patent specification (2) was cited by the respondent during the hearing against the novelty of claim 1 in the fourth auxiliary request. Citation (2) discloses a process for the sterilization of an article in an enclosed chamber which employs hydrogen peroxide as the low vapour pressure sterilant as the precursor for the active species generated during the plasma generation cycle by electrical discharges in the sterilant vapour.

The process in (2) (see especially column 5, line 46, to column 6, line 8) comprises the steps of

(1) placing the object or article to be sterilized in a (pre-treatment) vacuum chamber or into the plasma chamber;

(2) evacuating said chamber to a pressure of approximately 0.05 Torr;

(3) injecting an aqueous solution of hydrogen peroxide into the chamber and raising the pressure to from 0.5 to 10 Torr;

(4) allowing the object or article to remain in the

said chamber for a period of from 5 to 30 minutes;

(5) subjecting the object or article to be sterilized to a plasma generated by electrical discharges either in the pre-treatment chamber or in a separate plasma chamber;

(6) allowing the object or article to remain in the plasma for a period of from 5 to 60 minutes to effect complete sterilization.

Example VII in column 9 of citation (2) discloses a two cycle sterilization procedure. The first cycle is as described above. Thereafter the cycle is repeated by repeating steps (1) to (6) as described at columns 5 and 6 of citation (2).

8.3 The respondent suggested at the oral proceedings that the feature of exposing, in step (5) of the above treatment cycle, the article to be sterilized to a plasma generated by electrical discharges in the sterilant vapours would correspond to step (d) in claim 1 of the claimed process. The board cannot agree. Neither does citation (2) disclose the requirement of introducing a gas different from the vapour sterilant into the chamber nor is the raising of the pressure in the chamber up to atmospheric pressure to compress the vapour sterilant anywhere disclosed in the cited document.

Consequently, apart from the fact that step (f) in the claimed process requires at least **two** repetitions of the treatment cycle, whilst the disclosure in Example VII of citation (2) refers to one or two treatment cycles and accordingly to **one** repetition only (as

agreed by the respondent), citation (2) contains no disclosure of the particular technical features of step (d) of the claimed process. Certainly, it cannot be said that there is any direct and unambiguous disclosure in citation (2), whether explicit or implicit, of all technical features of the claimed process in claim 1 of the fourth auxiliary request. Novelty of the claimed subject matter in the fourth auxiliary request within the meaning of Article 54(1) EPC is therefore acknowledged.

Remittal to the department of first instance (Article 111(1) EPC)

In accordance with decisions G 9/91 and G 19/91 (OJ EPO 1993, 408 and 420, see in particular reasons, point 18) the essential function of an appeal is to consider whether the decision which has been issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the departement of first instance. It is the well-recognised practice of the EPO that any party should normally be given the opportunity to have all the important elements of the case considered by two instances.

In particular, remittal is considered by the boards where a first-instance department issues a decision relating solely to one particular issue decisive for the case against a party and leaves other essential issues undecided. If, following appeal proceedings, an appeal on this particular issue is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues. In the present

case, the opposition division revoked the patent for lack of novelty but did not consider the opposition under Article 100(a) on the ground of lack of inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution.

The Registrar: The Chairman:

A. Townend P. A. M. Lançon