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D E C I S I O N
of 28 May 1998

Case Number: T 0101/95 - 3.3.2

Application Number: 88112384.8

Publication Number: 0302420

IPC: A61L 2/20

Language of the proceedings: EN

Title of invention:
Low pressure hydrogen peroxide vapor sterilization system

Patentee:
Johnson & Johnson Medical, Inc.

Opponent:
American Sterilizer Company

Headword:
Low-pressure sterilisation/JOHNSON & JOHNSON MEDICAL

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes): not suggested range of pressure"

Decisions cited:
-

Catchword:
-

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Case Number: T 0101/95 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 28 May 1998

Appellant: (Proprietor of the patent)
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Respondent: (Opponent)
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Representative:
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 5 December 1994 revoking European patent No. 0 302 420 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: C. Germinario
R. E. Teschemacher

Summary of Facts and Submissions

I. European Patent No. 0 302 420 was granted in response to European patent application No. 88 112 384.8 on the basis of a set of 6 claims.

The text of claim 1 reads as follows:

"A process of vapor sterilization of articles comprising the steps of:

a) placing an article to be sterilized into a sterilization chamber,

b) evacuating said chamber,

c) creating a hydrogen peroxide atmosphere in the chamber and allowing the hydrogen peroxide vapor to contact the article,

d) maintaining the chamber at a low pressure for a period of time sufficient to achieve sterilization,

characterized in that

- the chamber is evacuated to a pressure below 1.33 mbar (1.0 torr),
- the hydrogen peroxide is introduced into the chamber in the form of an aqueous solution,
- the concentration of hydrogen peroxide vapor contacting the article is in the range of from about 0.1 to about 10 mg/l, and
- the chamber is maintained at a temperature of less than about 40°C and a pressure below the vapor pressure of hydrogen peroxide during the sterilization process."

II. Notice of opposition was filed by the respondent, requesting revocation of the patent in its entirety on the grounds of insufficiency of disclosure and lack of inventive step.

The following documents, cited during the proceedings before the opposition division, are relevant for the present decision:

(2) US-A-4 169 124

(3) US-A-4 512 951

(11) Affidavit of D. R. Gagne

III. The patent was revoked by the opposition division pursuant to Article 102(1)EPC.

Having recognised that the invention was novel and was disclosed in a manner sufficiently clear and complete to be carried out by the skilled person, the opposition division identified in document (2) the closest prior art. This document disclosed a sterilisation process using low concentration hydrogen peroxide in gas form, operating at negative pressure. The difference recognised by the opposition division between the process of (2) and the claimed one lay in the higher operating pressure characterising the prior-art process.

The opposition division held that the relationship between the sporicidal activity of H_2O_2 solutions and the pressure in the sterilisation chamber, in the sense

that decreasing the pressure would improve the sterilisation activity, was clearly recognised in the prior-art documents (2) and (3). On the other hand, the division maintained that the alleged dramatic increase in sterilisation efficiency reported in the patent was based on results obtained by faulty methodology. This opinion was mainly based on the experimental data enclosed in the Gagne affidavit, document (11).

Gagne argued that the poor sterilisation efficiency observed with pressure higher than 1.0 torr illustrated in example I of the patent, was to be attributed to the failure to vaporise the sterilant completely at high pressure or to other experimental conditions followed by the appellant. In fact, having introduced into the process an additional step of pre-vaporisation of the sterilant, Gagne reported the complete sterilisation of the majority of the test samples in a wide range of pressures, and also at values higher than 1 torr.

IV. The appellant (patentee) lodged an appeal against this decision. Oral proceedings were held on 28 May 1998.

The appellant contested, in writing and during the oral proceedings, the reliability of the results disclosed by Gagne, and stressed that having introduced an additional step of pre-vaporisation of the sterilant, Gagne failed to reproduce the conditions of the claimed process. For this reason the reported results were not comparable with those in the patent.

The appellant's arguments in support of the inventive merit of the invention are the following. At the very

low operating pressure according to the invention, not only the sporicidal activity of hydrogen peroxide but also the influence of its concentration on the final sterilisation effect are dramatically increased, as illustrated in the patent. He also stresses that all the cited prior documents teach, in order to improve the sterilisation activity of hydrogen peroxide, either the application of a moderately negative pressure during the sterilisation run or the increase of temperature or the use of a vaporiser. However, no prior document suggests to the skilled reader that the pressure should be decreased to the range of values according to the invention.

V. The respondent submitted in writing and during the oral proceedings the following arguments.

Documents (2) and (3) disclose sterilisation processes operating at low pressure in order to improve the sterilisation activity of a solution of hydrogen peroxide.

Therefore, in the respondent's view, documents (2) and (3) would suggest to the skilled person that the pressure in the sterilisation chamber should be decreased in order to improve the sterilisation effect. Moreover, bearing in mind that the vapour pressure of a highly concentrated solution of hydrogen peroxide tends to be 1 torr, the choice of this value as the highest value in the step of injecting the sterilant solution would be obvious to the skilled person.

Finally, the poor sterilisation effect observed in the

patent disclosure upon injection of the hydrogen peroxide at a pressure higher than 1 torr, could easily be explained with the incomplete vaporisation of the sterilant solution.

VI. The appellant requested that the decision under appeal be set aside and the patent be maintained as granted.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Article 100(b) has been cited as one of the grounds for opposition. During the written phase of the appeal proceedings, the respondent (opponent) discussed this point only in passing, and the objection of insufficient disclosure was no longer argued during the oral proceedings.

The Board does not see any valid reason for deviating from the position taken by the opposition division. Therefore the patent is considered to comply with the requirements of Article 83 EPC.

Novelty was not at issue in the present case.

3. *Inventive step*

3.1. Both the parties recognise in document (2) the closest prior art. The Board shares this opinion.

This document describes a sterilisation process using low-concentration hydrogen peroxide in gas form at low temperature, ie below 80°C, for a sterilisation time ranging, under different conditions from 10 minutes to 2 hours or 60 seconds to 1 hour. The sterilant solution is introduced into the sterilisation chamber, which is then evacuated to create a negative pressure. The negative pressure applied is preferably greater than 15 inches of Hg (381 torr/ 506.73 mbar) but it does not exceed 25 inches of Hg (635 torr/ 844.5 mbar)(see claim 1, column 3, lines 2 and 3 and examples 1 to 5). According to example 5, a specimen of 10^6 mature spores of *Bacillus subtilis var niger* was subjected to the sterilisation process with 1.4 mg H_2O_2/L. After 1 hour at 22°C and at a pressure value of 25 inches Hg (635 torr), complete sterilisation is reported (see column 2, lines 50 to 56). Complete sterilisation is also reported in all the other examples.

The main difference acknowledged between the process according to example 5 of document (2) and the claimed one lies in the higher operating pressure characterising the prior art, all the other relevant parameters of the process, namely concentration of the sterilant in the chamber, temperature and time being identical.

3.2. In the light of document (2), the problem underlying the present invention is to devise a sterilisation process with improved sterilisation efficiency.

3.3. The solution proposed by the patent is that of evacuating the sterilisation chamber, before injecting the sterilant,

to an initial pressure below 1.33 mbar (1.0 torr) and prosecuting the sterilisation at a pressure below the vapour pressure of hydrogen peroxide.

3.4. The technical effect achieved by this measure is reported in examples I to V and figures 2 and 3 of the patent.

Examples I and II show that an initial pressure (table I) and final pressure (table II) below 1.0 torr and 15 torr respectively cause, both, a dramatic improvement of the sporicidal activity of hydrogen peroxide as compared to the effect observed when the sterilisation is carried out at higher initial and final pressure, ie 1.0 to 5 torr, and above 15 torr respectively. Bearing in mind that the process according to document (2) is performed at a still higher pressure, namely 381 to 635 torr, the improvement in the sterilisation effect achieved by the present invention will be even more meaningful when compared with the process of the closest prior art.

This improvement observed at low pressure was not contested by the respondent. Therefore, on the basis of the results reported in the patent, the board can conclude that the solution proposed by the patent at issue actually solves the above-identified underlying technical problem.

3.5. In assessing whether this solution is obvious in the light of the prior art, the board first considers the teaching given by the closest prior art, ie document (2).

3.5.1 As pointed out by the respondent, this document discloses (see column 3, lines 4 to 17) that, at low pressure, the water having a greater partial pressure in the vapour phase

than the hydrogen peroxide evaporates more rapidly leaving the solution more concentrated in hydrogen peroxide. It goes on to suggest that, as the evaporation of the H_2O_2 solution continues in the sterilisation chamber, a greater hydrogen peroxide to water ratio enters the gaseous phase, with the effect that the sporicidal activity of the sterilant is improved. Therefore the vacuum, while facilitating a quick evaporation of the solution, would strongly increase the sporicidal activity.

This suggestion to operate the sterilisation at negative pressure clearly must be considered within the specific and complete technical teaching given in (2). The content of the above-cited passage is indeed further specified in the examples and in the paragraph bridging columns 2 and 3, where the values of pressure are said to range from 15 to 25 inches of Hg (ie from 381 to 635 torr), which however represents values several hundreds times higher than the values given in the patent claim 1.
The skilled reader of (2), however, could not find, beyond the generic teaching of running the sterilisation at slightly negative pressure, any suggestion to decrease both the initial and final pressure so drastically to operate at the same conditions stated in claim 1 under consideration.

Moreover, since satisfactory sterilisation is reported in all the examples of document (2), no motivation would be found by the skilled reader for investigating whether any change in the conditions disclosed in (2) could somehow improve the sterilisation effect of the gaseous hydrogen peroxide.

In conclusion, this document, taken alone does not make the

present invention obvious.

3.5.2 Document (3) was also cited by the respondent during the appeal proceedings. This document describes a method of hydrogen peroxide sterilisation, in which a vapour mixture comprising the sterilant is brought into contact with the articles to be sterilised and then caused to condense as a liquid film on said articles. The sterilisation chamber is evacuated to an absolute pressure of between 2 and 4 inches of Hg (ie 50.8 to 101.6 torr), then the pre-vaporised H_2O_2 solution is permitted to flow into the chamber (see column 4, lines 18 to 20). According to the paragraph bridging columns 1 and 2, the notable sporicidal action of gaseous hydrogen peroxide may be explained by the fact that the preliminary evacuation of the sterilisation chamber allows the gaseous sterilant to diffuse into the articles to be sterilised without being impeded by the air. The respondent's view was that this passage suggests to the skilled person a decrease of pressure in the sterilisation chamber to the values cited in claim 1 of the patent under appeal.

Beyond other differences such as a pre-vaporisation step, the board notes that the pressure values disclosed in (3) are considerably higher than both the initial and final pressure according to claim 1 under consideration, and that the document gives no hint why the conditions disclosed therein should be changed in order to achieve any improvement. On the contrary, bearing in mind the nature of the sterilisation method described in (3), which implies the introduction of the sterilant as a vapour and the subsequent condensation of the vapour to form a liquid film on the articles to be sterilised, the skilled reader would never consider it advantageous to decrease the pressure in the chamber below the reported values, since an increase in vacuum would certainly retard or even prevent the vapour from condensing and finally performing its sporicidal activity.

In consideration of the specific method disclosed in (3), which is substantially different from the process according to document (2), the board is also of the opinion that the skilled person could not find anything in (3) to suggest modifying the process according to (2) so as to reproduce the conditions stated in claim 1 of the opposed patent.

Therefore, this document, when taken alone or in combination with (2), does not make the present invention obvious.

3.6 In addition to the arguments already considered in the preceding paragraphs, the respondent expressed the opinion that the high sterilisation activity of hydrogen peroxide at a pressure below 1.0 torr was predictable for the skilled person, since the partial vapour pressure of a highly concentrated solution of hydrogen peroxide does tend to be 1.0 torr. As seen above, such a highly concentrated solution is obtained upon injection into the chamber of the commercial H_2O_2 solution (30%), and results from the quicker evaporation of water compared with the evaporation of the hydrogen peroxide.

The board recognises that the evident, dramatic increase in the sterilisation activity of H_2O_2 obtained when operating at the claimed conditions cannot, in itself and automatically, endow the claimed process with inventive merit. If, in fact, the prior art had suggested to the skilled person a decrease of the sterilisation pressure below 1.0 torr (or 15 torr as final pressure), the achievement of an unpredictably higher effect obtained while reducing this suggestion to practice would be regarded as an additional effect (bonus effect) obtained automatically without exerting an inventive effort.

However, as seen in the preceding paragraphs, none of the prior art documents, taken alone or in combination, suggests decreasing the pressure in order, at least, to approach the claimed values. Therefore the inventive step involved in the process of claim 1 is recognised, regardless of the level of the sterilisation effect achieved by the process.

In conclusion the claimed subject-matter involves an

inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside

2. The patent is maintained unamended.

The Registrar: The Chairman:

P. Martorana U. Oswald