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Datasheet for the decision of 21 September 2011

Case Number: T 0044/10 - 3.2.07

Application Number: 03774421.6

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Title of invention:
Device and method for sterilizing packages

Patentee:
Tetra Laval Holdings & Finance SA

Opponent:
KRONES AG

Headword:
-

Relevant legal provisions:
EPC Art. 56, 114(2)
RPBA Art. 13(1)(3)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Inventive step (all requests): no"
"Late-filed new auxiliary request 3: admitted"

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-

Catchword:
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Case Number: T 0044/10 - 3.2.07

D E C I S I O N
of the Technical Board of Appeal 3.2.07
of 21 September 2011

Appellant: (Applicant)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 26 November 2009 revoking European patent No. 1572541 pursuant to Article 101(3)(b) EPC.

Composition of the Board:

Chairman: I. Beckedorf
Members: K. Poalas
H. Hahn

Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal against the decision of the Opposition Division revoking the European patent No. 1 572 541.

II. The Opposition Division found that the subject-matter of claim 1 according to one of the main and third to sixth auxiliary requests lacks inventive step over the teaching of D5 (WO-A-02 064174) and that the subject-matter of claim 1 according to one of the first and second auxiliary requests does not meet the requirements of Article 84 EPC.

III. Oral proceedings before the Board took place on 21 September 2011.

(a) The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted or, alternatively, that the patent be maintained in amended form on the basis of one of the sets of claims filed as auxiliary request 1a with letter of 1 April 2010, new auxiliary request 3 during the oral proceedings and auxiliary request 4 with letter dated 18 August 2011. The appellant withdrew its auxiliary request 1, filed with letter of 1 April 2010, auxiliary request 2, filed with letter of 18 August 2011, and new auxiliary request 2, filed during the oral proceedings. Furthermore, it stated that its new auxiliary request 3, filed during the oral proceedings, replaced its auxiliary request 3, filed with letter of 18 August 2011.

(b) The respondent (opponent) requested that the appeal be dismissed.

IV. Independent claims 1 according to the appellant's requests read as follows (amendments over claim 1 as granted are depicted in bold):

Main request

"A device for sterilization in production of packages (8), which is adapted for sterilization with a gaseous sterilizing agent kept in the gaseous phase throughout the sterilization process, said device comprising a first heating zone (2), a thereto connected second sterilization zone (3), and a third venting zone (4) connected to said second zone, characterised in that it further comprises means for maintaining a higher pressure in the sterilization zone (3) than in the heating zone (2) and venting zone (4)".

Auxiliary request 1a

"A device for sterilization in production of packages (8), which is adapted for sterilization with a gaseous sterilizing agent kept in the gaseous phase throughout the sterilization process, said device comprising: a first heating zone (2), a thereto connected second sterilization zone (3), and a third venting zone (4), connected to said second zone, characterised in that, it further comprises means for maintaining a higher pressure in the sterilization zone (3) than in the heating zone (2) and venting zone (4), **and**

means for controlling a flow of gaseous sterilizing agent in the sterilization zone (3), which are arranged to introduce the gaseous sterilizing agent in a top portion of the sterilization zone (3) and to evacuate the gaseous sterilizing agent in a bottom portion of the sterilizing zone (3), maintaining a flow of gaseous sterilizing agent essentially from top to bottom".

New auxiliary request 3

"A device for sterilization **in production of packages (8), which is adapted for sterilization of packages (8), before filling of the packages (8), said packages (8) having an open end (11) and a closed end (12),** with a gaseous sterilizing agent kept in the gaseous phase throughout the sterilization process, said device comprising:
a first heating zone (2), a thereto connected second sterilization zone (3), and a third venting zone (4), connected to said second zone,
wherein said zones (2,3, 4) are separated from each other by means of partitionings (6,7) having openings (6a, 7a) for the passage of packages (8),
characterised in that, it further comprises
means for maintaining a higher pressure in the sterilization zone (3) than in the heating zone (2) and venting zone (4),
means (17, 20) for controlling a flow of gaseous sterilizing agent in the sterilization zone (3), such that the gaseous sterilizing agent flows essentially in a direction from the open end (11) of the packages (8) towards the closed end (12) of the packages (8),
said means (17, 20) for controlling the flow of gaseous sterilizing agent are arranged to introduce the gaseous

sterilizing agent in a top portion (18) of the sterilization zone (3) and to evacuate the gaseous sterilizing agent in a bottom portion (19) of the sterilizing zone (3), maintaining a flow of gaseous sterilizing agent essentially from top to bottom, and a filling zone (5) for filling said packages (8), and means for maintaining a higher pressure in the filling zone (5) than in the venting zone (4),
said device further comprising means (21,24) for controlling a venting air flow in the venting zone (4), such that the venting air flows essentially in a direction from the open end (11) of the packages (8) towards the closed end (12) of the packages (8), wherein the means (21 ,24) for controlling the flow of venting air are arranged to introduce the venting air in a top portion (22) of the venting zone (4) and to evacuate the venting air in a bottom portion (23) of the venting zone (4), maintaining a flow of venting air essentially from top to bottom".

Auxiliary request 4

"A method of sterilizing packages (8) in production of the packages (8), said packages (8) having an open end (11) and a closed end (12), wherein the packages are first passed into a heating zone where they are heated to a temperature above the dew point of a sterilizing agent, wherein the gaseous sterilizing agent is used and kept in the gaseous phase throughout the sterilization process and, wherein a venting zone is provided,
characterised in that,
a positive pressure is maintained in a sterilization zone (3) in which the sterilization is performed so

that it may be ensured that any leakage of gas and air between the sterilization zone and the surrounding heating and venting zones is from the sterilization zone towards the surrounding zones,
wherein the gaseous sterilizing agent in the sterilization zone (3) flows essentially in a direction from the open end (11) of the packages (8) towards the closed end (12) of the packages (8),
wherein the gaseous sterilizing agent is introduced in a top portion (18) of the sterilization zone (3) and evacuated in a bottom portion (19) of the sterilization zone (3), so that a flow of sterilizing agent essentially from top to bottom is maintained,
wherein venting air in the venting zone (4) flows essentially in a direction from the open end (11) of the packages (8) towards the closed end (12) of the packages (8) and wherein the venting air is introduced in a top portion (22) of the venting zone (4) and evacuated in a bottom portion (23) of the venting zone (4), so that an air flow essentially from top to bottom is maintained, and
wherein a higher pressure is maintained in a filling zone for filling vented packages than in the venting zone (4)".

V. The appellant argued essentially and as far as it is relevant for the present decision as follows:

Claim 1 according to the main request - Inventive step, Article 56 EPC

The features of claim 1 that
a) the sterilization zone is connected to the heating zone, that

b) the gaseous sterilizing agent is kept in the gaseous phase throughout the sterilization process, and that
c) the device comprises means for maintaining a higher pressure in the sterilization zone than in the heating zone and venting zone
are not disclosed in D5.

The information on page 18, line 35 to page 19, line 4 of D5 insinuates that interface areas between the two chambers are additional areas present at the interface of the chambers, whereby only said areas and not the chambers are kept under pressure difference. Accordingly, the person skilled in the art cannot infer from the above mentioned passage of D5 the teaching that the decontamination chamber should be kept at a higher pressure than the aeration chamber.

In absence of any teaching in D5 towards avoiding cross-contamination of the decontamination chamber from the side of the heating zone by maintaining a higher pressure in the decontamination zone the person skilled in the art also cannot infer from D5 any teaching towards the provision of means for maintaining a higher pressure in the decontamination chamber than in the heating zone.

Claim 1 according to auxiliary request 1a - Inventive step, Article 56 EPC

The introduction of the gaseous sterilizing agent in a top portion of the sterilization zone and the evacuation of said sterilizing agent in a bottom portion of the sterilizing zone allows accurate

sterilization of the inside and the outside of the packages to be sterilised.

In absence of any teaching in D5 towards an accurate sterilization of the inside and the outside of the packages to be sterilised via the introduction of the gaseous sterilizing agent in a top portion of the sterilization zone the person skilled in the art would not provide means for introducing the gaseous sterilizing agent in a top portion of the sterilization zone without exercising an inventive activity.

Admissibility of new auxiliary request 3

New auxiliary request 3 has been filed with the intention to overcome the objections raised by the Board during the oral proceedings in connection with the question of the inventive step of the subject-matter of claim 1 of the auxiliary request 1a.

Therefore said request should be admitted into the proceedings.

Claim 1 according to new auxiliary request 3 - Inventive step, Article 56 EPC

There is no reference in D5 to means for maintaining a higher pressure in the filling zone than in the venting zone.

There exists also no reference in D5 towards the provision of means for a top-to-bottom ventilation within the venting zone. This kind of ventilation allows a direct removal of the impurities present on

the packages to be treated without the risk of having gas together with these impurities circulating within the venting zone.

Since none of the above mentioned means has been mentioned in D5, said document can also not give any incentive to the person skilled in the art for incorporating such means into the sterilisation device known from D5.

Claim 1 according to auxiliary request 4 - Inventive step, Article 56 EPC

The method according to claim 1 of auxiliary request 4 differs from the one known from D5 in that

i) a positive pressure is maintained in the sterilization zone so that it may be ensured that leakage of gas and air between the sterilization zone and the surrounding heating zone is from the sterilization zone towards the surrounding heating zone,

ii) the gaseous sterilizing agent is introduced in a top portion of the sterilization zone,

iii) venting air in the venting zone is evacuated in a bottom portion of the venting zone, and

iv) a higher pressure is maintained in the filling zone than in the venting zone.

Since none of the above mentioned method steps have been mentioned in D5, said document can also not give any incentive to the person skilled in the art for

incorporating said method steps into the sterilisation method known from D5.

Furthermore, said four additional method steps show a combinatorial effect beyond the sum of their individual effects.

VI. The respondent argued essentially and as far as it is relevant for the present decision as follows:

Claim 1 according to the main request - Inventive step, Article 56 EPC

The heating zone in the device according to figure 8 of D5 consists of the heating chamber 170 and the intermediate chamber positioned between the heating chamber and the decontamination chamber 11.

Both the decontamination chamber and the packages to be decontaminated are kept at a temperature higher than the dewpoint of the hydrogen peroxide vapour in order to avoid condensation of said gaseous sterilizing agent, see page 17, line 11 to page 18, line 2 of D5. Thus said gaseous sterilizing agent is kept in the gaseous phase throughout the sterilization process.

The device comprises means capable of maintaining a higher pressure in the sterilization zone than in the heating zone, whereby these means are the fill lines 172 and 178, the exhaust lines 174 and 183 and the pumps 176 and 184, see page 18, line 3 to page 19, line 4.

In order to avoid cross-contamination between the decontamination chamber 11 and the heating zone the person skilled in the art would maintain a higher pressure within the decontamination chamber than in the heating zone without exercising an inventive activity. The fill lines 172 and the pumps 176 for the decontamination chamber and the ventilation line 110 and the pump 112 shown in figure 1 are applicable to the heating chamber 170 of figure 8 and are also capable of being used as a means for achieving this effect.

Claim 1 according to auxiliary request 1a - Inventive step, Article 56 EPC

An alternative positioning for the inlet line 172 of figure 8 of D5 is shown in figure 11 of the same document, in the form of the inlet 200 positioned at a top portion of the decontamination chamber 11.

It is obvious that such positioning of the vapour inlet allows an equal decontamination treatment of both the inside and the outside of the packages. It is further obvious, since the inlet line 172 in figure 8 of D5 is positioned within the packages, that the inside of said packages is more intensively decontaminated than the outside of said packages.

Thus, the person skilled in the art would position the inlet line for the hydrogen peroxide vapour at a top portion of the decontamination chamber in order to enhance decontamination on the outside of the packages without exercising an inventive activity.

Admissibility of new auxiliary request 3

New auxiliary request 3 being submitted during the oral proceedings is a late-filed request and therefore it should not be admitted into the proceedings according to Article 114(2) EPC.

Claim 1 according to new auxiliary request 3 - Inventive step, Article 56 EPC

The person skilled in the art seeking to avoid cross-contamination of the filling zone from the side of the venting zone and inferring the removal of the impurities present on the packages and also seeking to prevent at the same time gas turbulences within the venting zone would regard the provision of means for maintaining a higher pressure in the filling zone than in the venting zone and for a top-to-bottom ventilation within the venting zone as a normal design option in order to solve the above mentioned problems.

Claim 1 according to auxiliary request 4 - Inventive step, Article 56 EPC

The method according to claim 1 of auxiliary request 4 differs from the one known from D5 in that

i) a positive pressure is maintained in the sterilization zone so that it may be ensured that leakage of gas and air between the sterilization zone and the surrounding heating zone is from the sterilization zone towards the surrounding heating zone,

ii) the gaseous sterilizing agent is introduced in a top portion of the sterilization zone,

iii) venting air in the venting zone is evacuated in a bottom portion of the venting zone, and

iv) a higher pressure is maintained in the filling zone than in the venting zone.

Each one of the above mentioned method steps is a trivial feature which the person skilled in the art would add to the method known from D5 depending on the circumstances without exercising an inventive activity.

No combinatorial effect exists between said four method steps.

Reasons for the Decision

1. *Claim 1 according to the main request - Inventive step, Article 56 EPC*

1.1 It is undisputed that D5 discloses a device for sterilization in production of packages 120, which is adapted for sterilization with a gaseous sterilizing agent (hydrogen peroxide vapour), said device comprising a first heating zone (heating chamber 170), a second sterilization zone (decontamination tunnel/chamber 11), and a third venting zone (aeration chamber 182) connected to said second zone.

1.2 The appellant argued that the features of the preamble of claim 1 that

a) the sterilization zone is connected to the heating zone, and that
b) the gaseous sterilizing agent is kept in the gaseous phase throughout the sterilization process,
are not disclosed in D5.

1.3 The Board considers that the above mentioned features a) and b) are known from D5 for the following reasons:

1.3.1 The Board notes that claim 1 refers to zones in general and not to chambers. Figure 8 of D5 shows an intermediate chamber positioned between the heating chamber 170 and the decontamination chamber 11. Said intermediate chamber is connected on the one side to the heating chamber 170 and on the other side to the decontamination chamber 11. Furthermore, according to page 17, line 33 to page 18, line 2 of D5 the packages are heated by the heaters 171 to a sufficient temperature such that the surfaces of the packages are at or above the temperature of the decontamination chamber when they enter said chamber. The decontamination chamber itself is at a temperature higher than the dewpoint temperature of the hydrogen peroxide vapour, see page 17, lines 24 to 29. This means that when said packages are transported by the conveyor system 122 from the heating chamber into the decontamination chamber they are kept at an elevated temperature through the intermediate chamber. The Board derives therefrom that both the heating chamber 170 and the intermediate chamber define a heating zone in the sense of claim 1. As shown in figure 8 of D5 said heating zone is in direct contact, i.e. connected with the decontamination chamber 11.
Feature a) is therefore known from D5.

1.3.2 On page 17, line 11 to page 18, line 2 of D5 it is stated that in order to reduce hydrogen peroxide residuals on the decontaminated packages the conditions within the decontamination chamber 11 and around the packages are carefully monitored and controlled to keep the vapour slightly above the dewpoint temperature. This maximises the rate of decontamination and reduces the risk of condensation. In order to obtain a temperature in the decontamination chamber higher than the dewpoint of the vapour, see page 17, lines 24 to 29, the packages are heated at or above the temperature of the decontamination chamber to avoid condensation on the packages, see page 17, line 33 to page 18, line 2. The monitoring and controlling of the conditions within the decontamination chamber is described in D5 in relation to the device according to figure 1 but it is obviously correspondingly applicable to the device according to figure 8. According to page 15, line 10 to page 16, line 25 the control system based on data gathered from a plurality of monitors 152, 153, said last monitoring dewpoint, vapour concentration or pressure in the decontamination chamber, causes the vaporizer to modify the dew point of the vapour produced in order to ensure that condensation does not occur. Also the expression on page 17, lines 19 to 24 that the process is so controlled that the risk of condensation is reduced is to be read in the sense that the majority of decontamination treatments of the packages take place without any condensation during the sterilization process.

Accordingly, feature b) is also known from D5.

1.4 The Board establishes that according to page 18, line 23 to page 19, line 4 of D5 the (further) removal of the hydrogen peroxide from the packages takes place in the aeration chamber 182 which is subjected to a negative pressure, whereby *inter alia* a pressure difference between the decontamination chamber 11 and the aeration chamber may be used to minimise the risk of cross-contamination.

1.5 In the Board's perception the above mentioned passage of D5 teaches the person skilled in the art that pressure difference between the decontamination chamber and the aeration chamber avoids cross-contamination between said two chambers and the presence of a negative pressure in the aeration chamber enables the (further) removal of the vapour hydrogen peroxide from the packages. This means that in normal use the decontamination chamber is set under higher pressure than the pressure present in the aeration chamber. Means capable of subjecting the aeration chamber to negative pressure in comparison with the decontamination chamber, i.e. means for creating a situation with higher pressure in the decontamination chamber than in the aeration chamber are already present in the aeration chamber in form of the exhaust line 183 and the vacuum pump 184. Thus during normal use of the device according to figure 8 the vacuum pump 184 and the exhaust line 183 can create a negative pressure difference between the two chambers whereby at the same time the pump 176 and the file lines 172 and exhaust lines 174 as described on page 18, lines 3 to 22, being correspondingly adapted would maintain said pressure difference. Accordingly, means capable of maintaining a higher pressure in the decontamination

chamber than in the aeration chamber are present in said device.

1.6 The appellant argues that the information on page 18, line 35 to page 19, line 4 of D5 insinuates that interface areas between the two chambers are additionally present at the interface of the chambers, whereby only said areas and not the chambers are kept under pressure difference.

1.7 The Board cannot find in the above-mentioned passage any support for the appellant's allegation. Moreover, the Board reads said passage as defining three possibilities for minimising the risk of cross-contamination:
a) a pressure difference between the decontamination chamber and the aeration chamber is created,
b) air flow through filters, such as HEPA filters, takes place, whereby said filters are positioned in the interface areas between the decontamination tunnel and the aeration chamber,
c) a combination of a) and b).
Accordingly, possibility a) defines explicitly the use of a pressure difference between the decontamination chamber and the aeration chamber.

1.8 Since the presence of a higher pressure in the decontamination chamber than in the heating zone chamber is nowhere mentioned in D5 the Board considers further that this characterising feature of claim 1 is not known from D5.

1.9 The effect of this differentiating feature is that due to the presence of higher pressure in the

decontamination chamber cross-contamination of the said chamber from impurities present in the heating zone is prevented.

1.10 The Board establishes that it is well known to the person skilled in the art that one of the most common ways for avoiding cross-contamination of a chamber from its neighbourhood is to put said chamber into higher pressure than the pressure present in its neighbourhood. This fact was also acknowledged by the appellant at the oral proceedings.

1.11 The Board considers that the person skilled in the art having in mind the general technical knowledge mentioned under point 1.10 above and seeking to avoid cross-contamination of the decontamination chamber not only from the side of the aeration chamber but also from the side of the heating zone would provide a higher pressure in the decontamination chamber without exercising an inventive activity. The suction pump 112 of figure 1 of D5 depicted as being positioned next to the heater 116 can be used as model for positioning corresponding means in the heating zone shown in figure 8 in order to create therein a pressure lower than the one present in the decontamination chamber. In such a case the correspondingly adapted use of the pump 176 and the file lines 172 and exhaust lines 174 in the decontamination chamber are capable of maintaining said pressure difference. Accordingly, means for maintaining a higher pressure in the decontamination chamber than in the heating zone would be also provided by the person skilled in the art seeking to solve the above-mentioned problem of cross-contamination without the exercise of any inventive activity.

1.12 For the above mentioned reasons the subject-matter of claim 1 does not involve an inventive step and thus it does not meet the requirements of Article 56 EPC.

2. *Claim 1 according to auxiliary request 1a - Inventive step, Article 56 EPC*

2.1 Claim 1 according to auxiliary request 1a differs from claim 1 according to the main request in that the device further comprises "means for controlling a flow of gaseous sterilizing agent in the sterilization zone, which are arranged to introduce the gaseous sterilizing agent in a top portion of the sterilization zone and to evacuate the gaseous sterilizing agent in a bottom portion of the sterilizing zone, maintaining a flow of gaseous sterilizing agent essentially from top to bottom".

2.2 The Board notes that in the device depicted in figure 8 of D5 pumps 176 and valves 178, 180 are used not only for introducing hydrogen peroxide vapour into the decontamination chamber 11 but also for evacuating said sterilizing agent out of said chamber and for controlling the flow of said agent within said chamber, see page 18, lines 3 to 22. Furthermore, as it can be seen by the arrows underneath the fill lines 172 the flow of said agent within the decontamination chamber is essentially from top to bottom.

2.3 As it is depicted in figure 8 the hydrogen peroxide vapour is evacuated via the lower opening of the exhaust lines 174 at a level near the bottom of the

packages, i.e. in a bottom portion of the decontamination chamber.

2.4 Accordingly, the only feature out of the additional features of claim 1 according to auxiliary request 1a which is not disclosed in the device shown in figure 8 of D5 is that the sterilising agent is introduced in a top portion of the decontamination chamber. According said figure 8 the hydrogen peroxide vapour is introduced into said chamber via the lower opening of the fill lines 172. Said opening is positioned within the packages and at a level lying next to the opening of the packages.

2.5 The Board notes that in the alternative sterilisation device shown in figure 11 of D5 the hydrogen peroxide vapour is introduced via the fill line 200 at a top portion of the decontamination area. It is obvious to the person skilled in the art that the positioning of the inlet for the sterilising agent at a top portion of the decontamination area increases the sterilisation effect at the outside of the packages in comparison with the introduction of the sterilisation agent at a point lying within said package as this is the case in the device shown in figure 8.

2.6 For that reason the Board is persuaded that the person skilled in the art seeking to achieve accurate sterilisation also of the outside of the packages would position the outlet of the fill lines 172 shown figure 8 at a position lying at a top portion of the decontamination area without exercising an inventive activity, especially since such an alternative way for introducing sterilising agent into the decontamination

chamber is already used in the sterilisation device according to figure 11 of the same document.

2.7 From the above the Board concludes that the subject-matter of claim 1 according to auxiliary request 1a also does not involve an inventive step and that it does not meet the requirements of Article 56 EPC.

3. *Admissibility of new auxiliary request 3*

New auxiliary request 3 was submitted by the appellant during the oral proceedings, which the respondent objected to as being filed late.

Claim 1 according to the new auxiliary request 3 is a combination of claim 1 of the auxiliary request 3 filed with letter dated 18 August 2011 and claims 2, 9 and 10 of the patent as granted. Thus no question of the respondent being unfairly taken by surprise arises, because it was aware of said possible feature's combination at least one month before the date of the oral proceedings and it had reasonably to expect that the appellant would have tried to overcome the inventive step objections by amendments.

The Board is satisfied that the new version of claim 1 is a *bona fide* attempt to overcome the objections raised by the Board during the oral proceedings in connection with the question of the inventive step of the subject-matter of claim 1 of the auxiliary request 1a.

Furthermore, the Board ascertains that new auxiliary request 3 does not raise issues which the Board or the

respondent cannot reasonably be expected to deal with without adjournment of the oral proceedings.

Under these circumstances the Board exercises its discretion and admits new auxiliary request 3 into the proceedings in accordance with Article 114(2) EPC and Article 13(1) and (3) RPBA.

4. *Claim 1 according to new auxiliary request 3 - Inventive step, Article 56 EPC*

4.1 Claim 1 according to new auxiliary request 3 differs from claim 1 according to auxiliary request 1a through additional features which have been added both to the preamble and to the characterising part of said claim.

The appellant did not dispute that the added features in the preamble of claim 1 are known from the sterilisation device according to figure 8 of D5. These do not therefore need to be taken into consideration by the assessment of inventive step.

4.2 The features added into the characterising part of claim 1 of new auxiliary request 3 which were not present in claim 1 according to auxiliary request 1a are that the device further comprises:

a) a filling zone for filling said packages, and means for maintaining a higher pressure in the filling zone than in the venting zone,

b) means for controlling a venting air flow in the venting zone, such that the venting air flows essentially in a direction from the open end of the

packages towards the closed end of the packages, wherein the means for controlling the flow of venting air are arranged to introduce the venting air in a top portion of the venting zone and to evacuate the venting air in a bottom portion of the venting zone, maintaining a flow of venting air essentially from top to bottom.

4.3 Feature a)

4.3.1 A filling area 190 positioned next to the aeration chamber 182 is also present in the sterilisation device shown in figure 8 of D5. As established under point 1.10 above it is well known to the person skilled in the art that one of the most common ways for avoiding the cross-contamination of a chamber is to put said chamber into higher pressure than the pressure present in its neighbourhood. It is also well known to the person skilled in the art that the filling area is a very sensitive area in which aseptic packaging takes place and in which obviously any kind of cross-contamination has to be avoided.

4.3.2 Thus, the Board considers that the person skilled in the art seeking to avoid cross-contamination of the filling area 190 would provide means for maintaining a higher pressure in the filling zone than in the aeration chamber 182 without exercising any inventive activity.

4.4 Feature b)

4.4.1 According to figure 8 of D5 the packages 120 having a top opening 123 and a bottom end 132 are positioned

vertically on the conveyor system 122. On page 18, lines 32 to 35 of D5 it is stated that sterile air is blown into the aeration chamber through an air inlet line 188 to remove any remaining vapour from the packages. Figure 8 shows a vertical air inlet line 188, which is obviously connected with a pump and which blows sterile venting air downwards. This means that the venting air flows essentially in a direction from the open end of the package towards the closed bottom end of the package, i.e. it flows also essentially from top to bottom of the aeration chamber. The open lower end of the air inlet line 188 ends at a top portion of the aeration chamber so that the sterile venting air is introduced into the aeration chamber at a top portion of said chamber. The open lower end of the exhaust line 183 for evacuating the venting air is positioned also at a top portion of the chamber.

4.4.2 Thus, the means for controlling a venting air flow in the venting zone as defined in feature b) differ from the ones present in the aeration chamber of the device according to figure 8 of D5 in that the evacuation of the venting air takes place in a bottom portion of the aeration chamber.

4.4.3 Due to the fact that in the aeration chamber 182 of figure 8 of D5 the venting air is introduced and evacuated from the top portion of said chamber, air turbulences are developed in said chamber increasing the risk of impurities' circulation. Insertion of the venting air at a top portion of the aeration chamber in combination with the evacuation of the venting air from a bottom portion of said chamber avoids air turbulences

within said chamber and decreases the risk of impurities' circulation.

4.4.4 From the above it follows that the objective technical problem to be solved can be formulated as to avoid air turbulences in the aeration chamber of figure 8 of D5.

4.4.5 The Board has no doubts that it is well known to the person skilled in the art that, when introducing a pressurised gas into a chamber via an opening positioned at one wall of said chamber in order to treat objects positioned next to the opposite wall, as it is the case in aeration chamber of figure 8, the easiest and direct way of evacuating said gas without producing any turbulences within said chamber is the positioning of the exhaust opening for said gas at said opposite wall. Given the fact that in the aeration chamber of figure 8 the sterile air is inserted at a top portion of said chamber it is obvious to the person skilled in the art that the easiest and direct way of evacuating said gas without producing any gas turbulences would be the positioning of the exhaust line at a bottom portion of said chamber. Furthermore, evacuation of a treating gas via the bottom portion of a chamber is a well-known technique to the person skilled in the art, see for example the teaching of D16 (US-A-5 114 674), wherein the sterilizing gas is drawn out via the bottom outlet openings 19.

4.4.6 For this reason the Board considers that the provision of means for evacuation the venting air at a bottom portion of the aeration chamber of figure 8 does not demand from the person skilled in the art the application of inventive skills.

4.5 From the above it follows that the subject-matter of claim 1 according to new auxiliary request 3 does not involve an inventive step and that it accordingly does not meet the requirements of Article 56 EPC.

5. *Claim 1 according to auxiliary request 4 - Inventive step, Article 56 EPC*

5.1 D5 discloses a method of sterilizing packages 120 in production of the packages, said packages having an open end 123 and a closed end 132, wherein the packages are first passed into a heating zone (heating chamber 170 and intermediate chamber) where they are heated to a temperature above the dew point of a sterilizing agent (hydrogen peroxide vapour), wherein the gaseous sterilizing agent is used and kept in the gaseous phase throughout the sterilization process and, wherein a venting zone (aeration chamber 182) is provided, see points 1.1 to 1.3.2 above.

5.2 According to said known method a positive pressure is maintained in a sterilization zone (decontamination chamber 11) in which the sterilization is performed so that it may be ensured that gas leakage between the sterilization zone and the adjacent venting zone is from the sterilization zone towards the venting zone, see point 1.5 above. Moreover, the gaseous sterilizing agent in the sterilization zone flows essentially in a direction from the open end of the packages towards the closed end of the packages, see the arrows in chamber 11 of figure 8 showing the flow of the hydrogen peroxide vapour coming out of the lower opening of the fill line 172. The gaseous sterilizing agent is

evacuated at a bottom portion of the decontamination chamber and the flow of sterilizing agent within said chamber is essentially from top to bottom, see points 2.2 and 2.3 above. Venting air in the venting zone flows essentially in a direction from the open end of the packages towards the closed end of the packages, see point 4.4.1 above. The venting air is introduced in a top portion of the venting zone, so that an air flow essentially from top to bottom is maintained, see point 4.4.1 above. A filling zone for filling vented packages, said filling zone being positioned next to the venting zone is foreseen, see figure 8.

5.3 Thus, the method according to claim 1 of auxiliary request 4 differs from the one known from D5 in that

i) a positive pressure is maintained in the sterilization zone so that it may be ensured that leakage of gas and air between the sterilization zone and the surrounding heating zone is from the sterilization zone towards the heating zone,

ii) the gaseous sterilizing agent is introduced in a top portion of the sterilization zone,

iii) venting air in the venting zone is evacuated in a bottom portion of the venting zone, and

iv) a higher pressure is maintained in the filling zone than in the venting zone.

5.4 Feature i)

As already discussed under points 1.4 and 1.5 above, D5 proposes the creation of a negative pressure in the aeration chamber in order to avoid cross-contamination of the sterilisation chamber. This means that the sterilisation chamber is maintained at a positive pressure compared with the pressure present in the aeration chamber.

As already established under points 1.9 to 1.11 above, the person skilled in the art also seeking to avoid cross-contamination of the sterilisation chamber 11 of figure 8 from the side of the heating zone, said last consisting of the heating chamber 170 and the intermediate chamber, would apply a pressure in the sterilisation chamber which would be higher than the pressure present in the heating zone without exercising an inventive activity.

In such a case, due to the presence of a higher pressure within the sterilising chamber any leakage of gas between the sterilisation zone and the heating zone would automatically be towards the heating zone.

5.5 Feature ii)

The reasoning given under points 2.4 to 2.6 above is also applicable to feature ii). Accordingly, the introduction of the gaseous sterilizing agent at a top portion of the sterilization zone does not involve an inventive step.

5.6 Feature iii)

The reasoning given under point 4.4 above is also applicable to feature iii). Accordingly, the evacuation of the venting air in the venting zone from a bottom portion of the venting zone does not involve an inventive step.

5.7 Feature iv)

The reasoning given under point 3.3 above is also applicable to feature iv). Accordingly, the maintenance of a higher pressure in the filling zone than in the venting zone does not involve an inventive step.

5.8 The Board is, thus, of the opinion that each of the differences the present alleged invention makes in respect to the prior art is an obvious addition. It remains to be seen whether their combination required an inventive step. The appellant presented no arguments in support of its allegation concerning the presence of a combinatorial effect.

5.9 It is established case law of the Boards of Appeal of the EPO that two features interact synergistically if their functions are interrelated and lead to an additional effect that goes beyond the sum of the effects of each feature taken in isolation (cf. see Case Law of Boards of Appeal of the EPO, 6th Edition 2010, I.D.8.2.1). It is not enough that the features solve the same or similar technical problem(s) or that their effects are of the same kind and add up to an increased but otherwise unchanged effect. In the present case, maintenance of a positive pressure in the

sterilization zone ensures that no cross-contamination of said zone takes place, the introduction of the gaseous sterilizing agent from a top portion of the sterilization zone infers the decontamination of the outside of the packages, evacuating the venting air in the venting zone from a bottom portion of the venting zone avoids gas turbulences within said zone, and maintaining a higher pressure in the filling zone than in the venting zone avoids cross-contamination of the filling zone. In the Board's view the increase of purification of the sterilized packages according to the alleged invention is simply the sum of all the single method steps mentioned above. Hence, there is no additional effect going beyond what could be expected.

5.10 From the above it follows that the subject-matter of claim 1 according to auxiliary request 4 does not involve an inventive step and that it accordingly does not meet the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

G. Nachtigall I. Beckedorf