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D E C I S I O N
of 2 May 2006

Case Number: T 0105/04 - 3.4.02

Application Number: 95920585.7

Publication Number: 0762902

IPC: A61L 2/26

Language of the proceedings: EN

Title of invention:
Sterilization testing system using parametric measurements

Patentee:
MINNESOTA MINING AND MANUFACTURING COMPANY

Opponent:
MMM Münchener Medizin Mechanik GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
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Decisions cited:
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Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0105/04 - 3.4.02

D E C I S I O N
of the Technical Board of Appeal 3.4.02
of 2 May 2006

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 14 November 2003 concerning maintenance of European patent No. 0762902 in amended form.

Composition of the Board:

Chairman: A. Klein
Members: A. Maaswinkel
C. Rennie-Smith

Summary of Facts and Submissions

I. This appeal lies from the interlocutory decision of the opposition division dated 14 November 2003 concerning European patent No. 0 762 902 (based on application No. 95 920 585.7). In its decision the opposition division found that the subject-matter of claim 1 according to the main request was not novel over the disclosure in document E3, that the claims according to auxiliary requests 1 and 2 were not allowable under Article 84 EPC and that the claims of auxiliary request 3 met the requirements of the EPC. For the question of patentability the following documents were considered as relevant prior art.

E2: DE-A-1 492 398

E3: WO-A-93 21964

II. Against this decision the patent proprietor has lodged an appeal. The fee for the appeal was paid on 13 January 2004. The statement setting out the grounds of appeal was received on 24 March 2004. The proprietor requested that the decision be set aside and the patent be maintained in unamended form as granted. With its grounds of appeal the proprietor filed sets of claims according to a number of auxiliary requests and furthermore filed an auxiliary request for oral proceedings.

III. No observations or requests have been filed by the respondent (opponent).

IV. In a communication pursuant to Article 11(1) RPBA, annexed to a summons to oral proceedings, the board expressed its provisional opinion that the novelty of the subject-matter of claim 1 of the main request was in doubt.

V. In reply to this communication of 28 March 2006 the appellant filed new sets of claims according to a main request and auxiliary requests.

VI. In a letter dated 24 March 2006 the respondent requested that the appeal proceedings be continued in writing and announced that it would not take part in the scheduled oral proceedings.

VII. On 2 May 2006 oral proceedings were held. At the oral proceedings the appellant requested that the decision under appeal be set aside and that the patent be maintained as amended on the basis of the main request filed during the oral proceedings.

VIII. Claim 1 of the main request reads as follows:

"A sterilization testing system for determining the efficacy of a sterilization cycle in a sterilization chamber, said system comprising:

sterilant challenging means (12) for challenging the penetration of sterilant to a predetermined location within said sterilization chamber;

a first temperature sensor (36) for sensing a first temperature at a chamber reference point within said sterilization chamber;

a second sensor (34), said second sensor being either a temperature sensor or a moisture sensor or a

humidity sensor, for sensing a second environmental parameter at said predetermined location within said sterilization chamber;

a timer (66); and

data processing means (60) for analysing data from the sensing means;

wherein the system further comprises data recording means (64) for recording data from said sensors and said timer, and housing means (20; 20') for housing said sensors, said timer and said data recording means; the data processing means being connected to receive data from the data recording means and arranged to analyze said data to determine that a sterilization cycle is complete and in response thereto to determine whether said sterilant adequately penetrated said sterilant challenging means to said predetermined location during that sterilization cycle".

Claims 2 to 18 are dependent claims.

IX. The arguments of the appellant may be summarised as follows:

Claim 1 is directed to a sterilization testing system for determining the efficacy of a sterilization cycle in a sterilization chamber. To this aim the efficacy is determined using measurements of environmental conditions in at least two locations, namely at a chamber reference point within the sterilization chamber and at a location within the load or simulated load. At the chamber reference point a first temperature sensor for sensing a first temperature is arranged and at the challenging point a second sensor is located, which may be either a temperature sensor or

a moisture sensor or a humidity sensor. The basis for the amendments in claim 1 is in paragraphs [0015] and [0036] to [0040] of the patent specification, which respectively disclose the use of a temperature sensor, a conductivity sensor and a moisture sensor at the challenging point.

Document E3 discloses a method and an apparatus for improving the assurance of effective operation of sterilizers, especially those of the pre-vacuum type. In Figure 5 of E3 a test module 110 is shown including a test cavity 115 with a heat sink 112 provided within the test cavity between the opening 116 and a temperature sensor 122. A pressure sensor 124 may be optionally included, sensing the pressure at the location of the sensed temperature, i.e. at the location of the temperature sensor 112 (see page 12, lines 28 to 30 and Figure 6). A moisture sensor 126 may be embedded in the heat sink material 112 in the test module 110. Therefore in the device of E3 all sensors (temperature, pressure, moisture) are located within the test module and collect data at the challenging point. This also follows from the flow chart in Figure 10 and the description on page 18, second paragraph, to page 20, second paragraph, where the measured data T_1, P_1 and M_1 are compared to reference data to determine the quality of the steam (saturated or superheated). This also reveals an important difference to the apparatus according to the present invention, because the sterilization system in E3 does not include a first temperature sensor at a chamber reference point but uses a reference temperature T_r which can be a preselected reference or a calculated temperature and must be provided externally.

Furthermore E3 does also not disclose the functioning of the data processing means according to the invention as defined in claim 1, since claim 1 requires "data processing means ...arranged to analyze said data to determine that a sterilization cycle is complete and in response thereto ..." to determine adequacy of sterilization. Instead, an analysis of the flow chart in Figure 9 of E3 shows that the temperature T_1 is compared with the reference temperature. If the desired temperature has not been reached the flow diagram proceeds to a further YES/NO logic "time up?". This is not an analysis based on recorded data to determine that a sterilization cycle is complete, but rather simply an interrupt triggered by a particular pre-established reference time inputted into the program logic. As is clear from Figure 9, if this time is "up" sampling is discontinued and the system is directly stopped. Accordingly, the test system of E3 does not make any determination regarding sterilization efficacy "in response thereto".

The only further document considered in the opposition proceedings, document E2, discloses a sterilization device with a specific built-in control system and is not a sterilization testing system, therefore it relates to a different type of device. The object in E2 is to provide a sterilizing device in which a safe sterilization is obtained in the shortest possible time with the help of a simple controlling device (paragraph bridging pages 3 and 4). This controlling device comprises (see claims 1 and 2 of E2) two temperature sensors, from which one (25 in Figure 2) is easily accessible, and the second (20 in Figure 2) is shielded. Their outputs are compared until it is established that

both temperatures are within a predetermined limit and the values are not recorded. Once adequate temperature conditions are reached the outputs of the sensors are no longer followed, but the device switches off after a predetermined time period. Therefore the subject-matter of claim 1 is novel over the disclosures in documents E2 and E3.

The subject-matter of this claim also involves an inventive step for the following reasons. If document E3 is considered as the closest prior art, the technical problem to be solved with respect to E3 can be considered to be the provision of an improved sterilization system which can independently and autonomously determine the efficacy of a sterilization cycle, in particular without having to use or input sterilizer-specific and/or mode-specific reference parameters. In contrast to the system according to the invention, the sterilizer disclosed in E3 is not a stand-alone system, because it requires the input from pre-established data (for instance, for the reference temperature). Since document E3 teaches that all sensors are arranged at the same location (namely at the challenging means) it teaches away from using two sensors at different locations. Furthermore the arrangement in document E3 has the disadvantage that since it only relies on a reference temperature, a drop in the temperature of the steam at the input of the chamber is not directly noticed. Therefore the subject-matter of claim 1 is not obvious in the light of E3.

Document E2 does not provide any suggestions how this technical problem can be solved, since it is completely silent with regard to any determination of the efficacy

of sterilization. The two temperature sensors are only an integral part of the control system used to control the operation of the sterilizer, i.e. to perform the sterilization in the shortest possible time. Finally document E2 is silent in regard to any determination of the efficacy of a sterilization cycle at the end of the cycle, therefore even a combination of E3 and E2 does not make the invention as defined in claim 1 obvious to the person skilled in the art.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

The board is satisfied that the amendments in claim 1 are fairly supported by the passages in the patent specification referred to by the appellant which have corresponding passages in the original application documents.

3. *Novelty*

3.1 Document E3, see Figure 1 discloses a sterilization testing system 100 for determining effective operation of a sterilizer chamber 200 (see page 1, 1st paragraph and Abstract). The testing system comprises sterilant challenging means for challenging the penetration of sterilant to a predetermined location (test cavity 115 including heat sink 112, see Figure 5 and page 12) within the sterilization chamber; and a sensor, the sensor being either a temperature sensor (122) or a

moisture sensor (126) for sensing an environmental parameter at the predetermined location within the sterilization chamber. The system includes a timer 144 (see also Figure 10) and data processing means 142, 146 (Figure 7; or external controller 300, see Figure 3) for processing data from the sensing means (temperature, pressure, moisture) and it may comprise data recording means for recording the data (page 11, lines 12 to 15). Furthermore the system includes housing means (100) for housing the sensors, timer and data recording means. The data processing means (controller 300) is connected to receive (receiver 320, Figure 8) data from the data recording means and arranged to analyze the data to determine that a sterilization cycle is complete (page 19, last paragraph, referring to the flow chart in Figure 10).

According to this flow chart, after determination that the test time is over the process stops. Therefore there is no subsequent process step to determine whether the sterilant adequately penetrated the sterilant challenging means, rather a comparison of the measured temperature within the sterilant challenging means with the reference temperature T_r (and, optionally, of the pressure and moisture) is carried out within the control cycle in Figure 10. Therefore the subject-matter in claim 1 differs from the testing system disclosed in E3 in the additional temperature sensor located at a chamber reference point for sensing a first temperature within the sterilization chamber and in the additional processing steps after completion of the sterilization cycle to determine whether the sterilant adequately penetrated the sterilant challenging means.

3.2 Document E2 discloses a sterilizing apparatus having a chamber for the reception of articles to be sterilized and including control apparatus for the automatic operation of a sterilization process (page 1). According to the last paragraph of page 3, the purpose of the invention in E3 is to provide sterilizing apparatus which, with the help of a simple control apparatus, assures a safe sterilization within the shortest possible time. To this aim the apparatus comprises a control unit 5 consisting of a measuring and switching unit and an electric motor, which drives notched discs through magnetic clutches (pages 12, 2nd paragraph). The switching of unit 5 is controlled by differentially comparing the signals of an unshielded thermal sensor 25 and of a shielded thermal sensor 20. If the temperature values of both sensors and their temporal development are within predetermined tolerances the control unit 5 will complete the sterilization procedure.

The apparatus in E2 is therefore not a sterilization testing system of the type disclosed in the patent and in document E3, because it is a complete sterilization apparatus. Furthermore, the two thermal sensors are an integral part of the control and switching unit 5 and their signals are solely used as input to this unit for carrying out the respective steam input and evacuation phases. The apparatus disclosed in E2 does not include data recording means and data processing means connected and arranged in the manner as defined in claim 1.

3.3 The further documents originally referred to in the Notice of Opposition appear to disclose more remote prior art.

3.4 Therefore the subject-matter of claim 1 is novel (Art. 52(1) and 54 EPC).

4. *Inventive step*

4.1 The board concurs with the position of the opposition division and of the appellant that document E3 represents the closest prior art, since this document is directed to the same purpose or effect as the invention, namely to provide a test pack or unit to determine the efficacy of a sterilization cycle in sterilizers.

4.2 The subject-matter of claim 1 differs from the sterilizer test apparatus in E3 in the provision of a temperature sensor arranged at a chamber reference point; and in the particular process steps of the data processing system.

4.3 According to the appellant, the objective technical problem to be solved with respect to E3 resides in the provision of an improved sterilization system which can independently and autonomously determine the efficacy of a sterilization cycle without having to use or input sterilizer-specific and/or mode-specific reference parameters.

4.4 In document E3 for determining the effectiveness of operation of the sterilizer reference temperatures and, optionally, reference pressure and moisture data are

considered, see page 17, 2nd paragraph, page 19, 2nd paragraph and the flow chart in Figure 10. According to the passage on page 19, the reference temperature can be a predetermined temperature e.g. 285°F, or a calculated value based on a computed average of selected values from earlier runs, e.g., the last ten Bowie and Dick mode temperatures. It may also be selected according to the particular load mode, see claims 4 to 6, and its value is programmed in the microprocessor.

4.5 Since the selection of a reference temperature (and optionally reference pressure and moisture) is at the basis of the control process in document E3 and appears to be an essential feature (the feature being included in its independent claim 1) the person skilled in the art would not be led by the teaching of this document to consider including a further temperature sensor to be arranged at a reference point in the sterilization chamber, i.e. at a point outside the test cavity 115, which temperature sensor should replace the reference temperature data in the control process of the testing device of E3.

4.6 In the opinion of the board a combination of the teaching of E3 with that in document E2 is also not obvious, since the types of apparatuses in these documents are rather different: E2 discloses a complete sterilizer with a built-in steering and control unit which relies on the temperature data of two sensors. The signals of these sensors are exclusively used in the (rather simple) control unit, no further data processing or evaluation being disclosed. Document E3, on the other hand, concerns a test system to be used in

a sterilizer chamber. All sensors are located within the test module and the measured data are compared with reference values, to be entered by the operator in the microprocessor. It is not plausible that the skilled person would consider combining the teachings of these documents, at least not without the benefit of hindsight.

4.7 Apart from the absence of the temperature sensor located at a chamber reference point and which measures the temperature in the chamber (the so-called "external temperature"), document E3 also does not disclose the data processing steps in claim 1 which require that, after the step of determining, based on an analysis of recorded data, that the sterilization cycle is complete (steps 310 to 314 in the flow diagram in Figure 15 of the patent), the adequacy of the process (steps 316 to 318) is determined. Since in the latter steps the information of the external temperature sensor is used, (column 20, line 47) which sensor is not present in the system of document E3, it cannot be supposed that the skilled person would consider including such steps in the data processing of the system in E3. Nor does the prior art provide any hint at autonomously determining the completion of a sterilization cycle from an analysis of recorded data from the sensors.

4.8 Therefore the subject-matter of claim 1 involves an inventive step (Art. 52(1) and 56 EPC).

4.9 Claims 2 to 18 are dependent claims and equally fulfil these provisions.

5. Since the respondent did not file any observations or request and did not attend the oral proceedings the board does not see any reason for arriving at a different conclusion.

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 with the order to maintain the patent on the basis of the description, claims and drawings of the main request filed during the oral proceedings.

The Registrar: The Chairman:

M. Kiehl A. Klein