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**Datasheet for the decision  
of 30 March 2023**

**Case Number:** T 0078/19 - 3.3.10

**Application Number:** 06780013.6

**Publication Number:** 1901784

**IPC:** A61L2/18, A61L2/24

**Language of the proceedings:** EN

**Title of invention:**  
COLD STERILIZER

**Patent Proprietor:**  
IMS S.r.l.

**Opponent:**  
Cisa Production S.r.l.

**Headword:**

**Relevant legal provisions:**

**Keyword:**

**Decisions cited:**

**Catchword:**



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Case Number: T 0078/19 - 3.3.10

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.10**  
**of 30 March 2023**

**Appellant:**  
(Patent Proprietor)

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**Decision under appeal:**

**Decision of the Opposition Division of the  
European Patent Office posted on 17 October 2018  
revoking European patent No. 1901784 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chair** P. Gryczka  
**Members:** R. Pérez Carlón  
F. Blumer

## Summary of Facts and Submissions

- I. The appellant (patent proprietor) filed an appeal against the decision of the opposition division to revoke European patent No. 1 901 784.
- II. Notice of opposition had been filed on the grounds of added subject-matter (Article 100(c) EPC), insufficiency of disclosure (Article 100(b) EPC) and lack of novelty and inventive step (Article 100(a) EPC).
- III. This is the second appeal in this case. The patent had been revoked in earlier opposition proceedings on the ground in Article 100(b) EPC, and this decision then appealed by the patent proprietor. In its decision on that appeal (case T 494/13), the board had ordered that the opposition division's decision be set aside and the case remitted for further prosecution.
- IV. The documents filed include the following:
- D1 WO 2005/056060 A1
  - D2 CISA - ERS Endoscope reprocessing and storing system, 2004
  - D8 US 6,793,882 B1
- V. The appellant's main request in appeal corresponds to the first auxiliary request before the opposition division. Claim 1 reads as follows:

*"A cold sterilizer for endoscopes for surgical and diagnostic use, operating with sterilizing agents effective in the range 20-35°C, comprising the*

*following parts:*

- a) *a chamber, containing tanks (1) for deterging/ decontaminating and sterilizing chemical agents, equipped with closure means (2);*
- b) *a room - which is or contains a container (3) for flexible endoscopes, the container (3) being provided with means for its sealing, opening, joining to and disjoining from the sterilizer - equipped with closure means (4);*
- c) *means for the automatic and safe collection of the deterging and sterilizing chemical agents;*
- d) *means for the circulation of the above chemical agents, among the tanks (1), the container (3) and the endoscopes contained therein;*
- e) *means for assuring the circulation under pressure of said chemical agents;*
- f) *means for allowing the purging of channels of said endoscopes;*
- g) *means for recording and printing the reprocessing data,*

*characterized by the fact that it is further provided with:*

- h) *a plurality of compartments (5) substantially parallel thereamong and arranged substantially parallelly to side walls and to a sterilizer support base, equipped with individual or common closure means (6) and containing casings (7), provided with means for their sealing, opening, joining to and disjoining from the sterilizer, in which casings (7) rigid endoscopes (8) are stored;*

- i) *said circulation means including circulation of the chemical agents among the casings (7) and the endoscopes contained therein;*
- j) *means for detecting and controlling in real time the pressures exerted on channels of the fluxed endoscopes,*

*the container (3) for flexible endoscopes being either fixed and rigid or movable and soft."*

Claim 1 of the first auxiliary request requires the container (3) to be movable and soft.

Claim 1 of the second auxiliary request has the features of claim 1 of the first auxiliary request, and in addition requires

*"wherein inside said container (3) there are located eight joints for the related connections to a flexible endoscope to be treated and wherein it is possible to perform a tightness test".*

Claim 1 of the third auxiliary request has all the features of claim 1 of the second auxiliary request, and in addition

*"wherein each of said casings (7) has two joints only, being a fluid inlet joint and a fluid outlet joint."*

Claim 1 of the fourth auxiliary request requires the compartments (5) defined in feature h) of claim 1 to be three, and in addition that

*"the sterilizer is capable of concomitantly sterilizing three rigid endoscopes, with a maximum length of 50 cm, and one flexible endoscope".*

In addition to the features of claim 1 of the fourth auxiliary request, claim 1 of the fifth auxiliary request requires that

*"for each of the compartments (5) there is provided reprocessing cycle start/stop means".*

Claim 1 of the sixth auxiliary request requires, in addition, that container (3)

*"is located at the center of a top portion of the sterilizer and said three compartments (5) are located at the center of the sterilizer, at the bottom thereof".*

Claim 1 of the seventh auxiliary request has all the features of claim 1 of the first auxiliary request, and in addition requires the steriliser to be capable of concomitantly sterilising three rigid endoscopes, with a maximum length of 50 cm, and one flexible endoscope.

In addition to the features of claim 1 of the seventh auxiliary request, claim 1 of the eighth auxiliary request requires that for each of the compartments (5) there is provided reprocessing cycle start/stop means.

Claim 1 of the ninth auxiliary request adds the feature

*"wherein said container (3) is located at the center of a top portion of the sterilizer and said three compartments (5) are located at the center of the sterilizer, at the bottom thereof."*

Lastly, claim 1 of the tenth auxiliary request requires, in addition to the features of claim 1 of the

ninth auxiliary request, the following:

*"wherein on a side of the sterilizer there are located a backlit LCD, a printer for reporting the process, cycle start-stop keys and access to the electronic cards of the sterilizer, and wherein on the back of the sterilizer there are hydraulic connections for the sterilizer operation and a removable panel for accessing to the mechanics thereof."*

VI. The opposition division concluded that D1 did not disclose the features of claim 1 requiring:

- at least three casings/containers, and
- the casing/containers to include closure means.

The problem underlying the claimed invention was to provide a steriliser for endoscopes having increased capacity while preventing accidental removal of the steriliser casings. The solution proposed by claim 1 of the then first auxiliary request, which is the main request on appeal, was characterised by the number of casings/containers and the presence of closure means. Since the solution would have been obvious to a skilled person, it was not inventive.

The second and third auxiliary requests, which are the first and second auxiliary requests on appeal, did not contain any distinguishing feature over and above those of the then pending auxiliary request 1. Their subject-matter was thus not inventive either.

Lastly, the opposition division concluded that the then pending fourth and fifth auxiliary requests contained



subject-matter extending beyond the application as originally filed.

VII. The appellant's arguments were as follows:

The cold steriliser disclosed in document D1 was the closest prior art. In addition to the distinguishing features identified by the opposition division, the steriliser of D1 lacked a container (3) which was either fixed and rigid or movable and soft, and casings (7) in which rigid endoscopes were stored. The problem underlying the claimed invention was to provide a steriliser capable of treating not only flexible but also rigid endoscopes, in an effective and safe manner, with reduced structural complexity and more compactness. The claimed solution, which was characterised by a container (3) which was either fixed and rigid or movable and soft, by casings (7) in which rigid endoscopes were stored, and by having three casings including closure means, would not have been obvious to a skilled person and was thus inventive.

VIII. The arguments of the respondent (opponent) were as follows.

The cold steriliser of D1 differed from that of claim 1 only by lacking three casings and closure means. The sole problem which could be regarded as solved by the claimed steriliser was to provide an alternative, and the solution would have been obvious to a skilled person in view of D1 alone.

Most of the appellant's auxiliary requests should not be admitted. If admitted, the appellant had not provided arguments as to why the conclusion on inventive step should differ from that on claim 1 of

the main request.

- IX. The board informed the parties in a communication dated 14 August 2020 that it was likely to conclude that the claimed steriliser was not inventive. Its preliminary view was that the appeal should be dismissed.
- X. The parties replied to the board's communication by announcing their non-attendance at the oral proceedings to which they had been summoned, which were cancelled.
- XI. The parties' final requests were as follows:
- The appellant requested that the decision under appeal be set aside and the patent maintained in the form of either the main request or one of auxiliary requests 1 to 10, all requests being as filed with the statement of grounds of appeal.
  - The respondent requested that the appeal be dismissed.

### **Reasons for the Decision**

1. The appeal is admissible.
2. Inventive step
  - 2.1 Claim 1 of the main request relates to a cold steriliser which comprises a container (3) for flexible endoscopes. This container is either fixed and rigid or movable and soft. The cold steriliser of claim 1 has casings (7), plural, in which rigid endoscopes are stored.

## 2.2 Closest prior art

- 2.2.1 The parties agreed with the opposition division's conclusion that document D1 was the closest prior art. The board sees no reason to differ.

D1 discloses a system for washing, sterilising and preserving endoscopes (page 1, lines 4 and 5), and in particular those having multiple channels held by a sheath (page 3, lines 18 and 19). The system of D1 has at least one case with hermetic closure (page 3, lines 21 and 22) and multiple connections 25 (figures 9 and 13) for the different channels of the endoscope. Six of the connections (25a to 25f) are for washing and sterilising (page 16, lines 12 and 13); connection 25g is for performing a tightness test (page 16, line 13).

The gist of the invention disclosed in D1 is the presence of a movable case, where an endoscope is not only sterilised but kept sterilised until use. The cases of D1, suitable to house all endoscopes by different manufacturers, are sealed by means of closures 23 (page 16, lines 3 to 6), made of plastic material, light, strong and non-deformable (page 15, line 32). They are thus "movable and rigid" to use the wording of claim 1.

The system of D1 preferably contains more than one case and is able to perform separate cycles for each of them (page 4, lines 5 to 7).

The device disclosed by the drawings of D1 contains two compartments for sterilisation, 11a and 11b.

- 2.2.2 The appellant argued that the sterilising device of D1 was suitable for flexible endoscopes, but not for rigid

ones.

However, the device of D1 is suitable for sterilising all endoscopes by different manufacturers (page 16, lines 3 to 5), thus including rigid endoscopes.

Document D2, which is a brochure for the respondent's commercial device CISA-ERS Endoscope Reprocessing and Storage System, which originates from D1, explicitly refers to sterilising both flexible and rigid endoscopes (page 3, lines 28 and 29). The application as originally filed refers to this ERS device from CISA, which can sterilise both types of endoscope (page 1, lines 33 to 36). The available evidence thus only corroborates what D1 discloses.

This argument of the appellant is thus not convincing.

### 2.3 Problem underlying the claimed invention

The appellant formulated the problem underlying the claimed invention as to provide a cold steriliser

- capable of treating not only flexible but also rigid endoscopes
- in an effective and safe manner
- with reduced structural complexity and
- more compactness.

### 2.4 Solution

#### 2.4.1 The opposition division concluded that the proposed solution to the technical problem was characterised only

- by including at least three casings/containers for sterilising medical devices and

- in that the casings/containers included closure means.

The parties did not dispute that these features characterised the claimed invention. The appellant, however, saw further differences with respect to D1, namely

- including a container (3) that was either fixed and rigid or movable and soft and
- having casings (7) in which rigid endoscopes were stored.

2.4.2 The cases of the steriliser of D1 are suitable for all types of endoscope, and thus also for rigid ones. Therefore, the feature of claim 1 requiring casings (7) to store rigid endoscopes does not characterise the claimed solution.

2.4.3 The cases of D1 are of the type "rigid and movable". The feature requiring container (3) to be either fixed and rigid or movable and soft is thus not disclosed in D1.

2.5 Success of the claimed solution

2.5.1 D1 already solves the problem of being capable of treating both flexible and rigid endoscopes in an efficient and safe manner (see 2.2.2 above).

2.5.2 Lacking a direct comparison with the system of D1, the part of the problem relying on an improvement in terms of safety and efficiency cannot be considered credibly solved.

2.5.3 The claimed steriliser requires a container (3) which is either "fixed and rigid" or "movable and soft" and a total number of casings/containers of at least three.

These features neither reduce the structural complexity of the steriliser nor enhance compactness. Claim 1 requires not only an additional case, but an additional type of case.

2.5.4 Summarising:

- The part of the problem related to providing a cold steriliser capable of treating both flexible and rigid endoscopes in an effective and safe manner is already solved by the steriliser of D1.
- The alleged improvement in terms of reducing structural complexity and increasing compactness has not been credibly solved.

2.6 Reformulation of the technical problem

In accordance with case law, alleged but unsupported advantages cannot be taken into consideration in determining the problem underlying the invention. The technical problem as defined by the appellant thus needs to be reformulated.

In view of D1, the problem underlying the claimed invention can be seen only as providing an alternative steriliser suitable, like that of D1, for flexible and rigid endoscopes.

The claimed solution is characterised by

- including an additional container (3) for flexible endoscopes which is either fixed and rigid or movable and soft (hence the total number of casings is three or more), and
- by the casings/containers having closure means.

2.6.1 It was not disputed that the claimed steriliser credibly solves the problem of providing an alternative to the steriliser of D1.

2.7 It thus remains to be decided whether the proposed solution to the objective problem defined above would have been obvious to the skilled person in view of the prior art.

2.7.1 The use of closure means is an obvious measure for the skilled person in order to avoid contamination. D1 itself discloses the need for hermetic closure (page 16, lines 5 and 6). This part of the claimed solution would thus have been obvious to the skilled person seeking an alternative.

2.7.2 Adding a further movable casing to the system would also have been an obvious option to a skilled person seeking an alternative to the system of D1, which discloses "more than one". This part of the claimed solution would also have been obvious as an alternative to that of D1.

2.7.3 With respect to the embodiment requiring the container (3) to be movable and soft instead of movable and rigid like those of D1, the appellant does not rely on any specific advantage of this type of container other than allowing the sterilisation of flexible endoscopes. As discussed above (see point 2.2.2), the movable and rigid containers disclosed in D1 are also suitable for

this task.

Trying to obtain an alternative steriliser, a skilled person would have replaced the container's material with another also suitable for the intended use. Flexible materials are prior art in the field of sterilisation; see for example D8, column 3, lines 7 to 14, which discloses a container which can be deformed. The skilled person would thus have used that type of material and arrived at the claimed invention without requiring inventive skill.

2.8 Thus, the claimed steriliser is not inventive within the meaning of Article 56 EPC in view of D1.

3. Auxiliary requests

3.1 The appellant has not provided arguments on the issue of inventive step with respect to any of the auxiliary requests on file. Point 4 of the statement of grounds of appeal explains what amendments have been made. Point 6 states merely that arguments with respect to inventive step apply in the same manner as for the main request. Since the main request lacks inventive step the same conclusion applies to the auxiliary requests, regardless of their admissibility.

4. In view of the board's negative conclusion on the issue of inventive step, it is not necessary to decide on any other point.

## **Order**

**For these reasons it is decided that:**

The appeal is dismissed.



The Registrar:

The Chair:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated