

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 13 July 2017**

Case Number: T 0494/13 - 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 S.r.l.

Headword:

Relevant legal provisions:
EPC R. 111(2)
EPC Art. 100(b), 111(1)

Keyword:

Appealed decision - sufficiently reasoned (yes)

Grounds for opposition - insufficiency of disclosure (no)

Appeal decision - remittal to the department of first instance
(yes)

Decisions cited:

T 0409/91, T 0435/91, G 0003/14

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0494/13 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 13 July 2017

Appellant:
(Patent Proprietor)

IMS S.r.l.
Via Laurentina, 169
00040 Pomezia Rm (IT)

Representative:

Di Cerbo, Mario
Società Italiana Brevetti S.p.A.
Piazza di Pietra 38-39
00186 Roma (IT)

Respondent:
(Opponent)

CISA S.r.l.
Via E. Mattei SNC Angolo Via La Viaccia
55100 Lucca (IT)

Representative:

Capasso, Olga
De Simone & Partners SpA
Via Vincenzo Bellini, 20
00198 Roma (IT)

Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 4 February 2013
revoking European patent No. 1901784 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman P. Gryczka
Members: R. Pérez Carlón
C. Schmidt

Summary of Facts and Submissions

- I. The appellant (patent proprietor) lodged 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. The opposition division concluded that the invention as claimed in the main request then pending, which is the sole request in these appeal proceedings, was not disclosed in a manner sufficiently clear and complete for it to be carried out, as the patent did not contain the necessary information on how to determine the required flow and control scheme. The skilled person was thus faced with multiple possible implementations, and developing any of them required inventive skills.
- IV. Claim 1 of the main request reads as follows:
- "A cold sterilizer for medical devices, in particular 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 medical devices, 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 medical devices contained therein;
- e) means for assuring the circulation under pressure of said chemical agents;
- f) means for allowing the purging of channels of said medical devices;
- 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 medical devices (8) are stored;
- i) said circulation means including circulation of the chemical agents among the casings (7) and the medical devices contained therein;
- j) means for detecting and controlling in real time the pressures exerted on channels of the fluxed medical devices,

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

V. The arguments of the appellant relevant for the present decision were the following:

The contested decision was not sufficiently reasoned, as it merely provided a list of items which had not

been disclosed in detail in the patent in suit, argued that the description of the patent in suit was very limited and hinted at a very large number of possible implementations, without explaining why any of this prevented a skilled person from carrying out the invention. For these reasons, the opposition division had committed a procedural violation.

The patent in suit contained sufficient information enabling the skilled reader to determine the required flow paths and control means. The figures of the patent specification provided the required connections which already defined the flow paths for the claimed steriliser. The design of control means fell within the skills of the person of the art, who should have a basic knowledge of hydraulics. In addition, such means were already known in the art. For that reason, the claimed invention was sufficiently disclosed.

The appellant requested that the case be remitted to the opposition division if inventive step needed to be examined.

VI. The arguments of the respondent relevant for the present decision were the following:

The contested decision was sufficiently reasoned as it explained that a flow and control scheme was necessary for implementing the claimed invention. The chain of reasoning of the opposition division was clear enough, and thus no procedural violation was apparent.

The claimed invention was not sufficiently disclosed, if only for the reasons given by the opposition division in the contested decision, as the patent in suit was silent on the "means for detecting and

controlling in real time the pressures exerted on channels of the fluxed medical devices" required by feature j) of claim 1. In addition, Figure 2 did not indicate how to connect a rigid endoscope to the fluid inlet depicted, which prevented the skilled reader from determining how to place the required pressure and controlling means. Also for this reason, the skilled person did not have information about how to obtain the claimed steriliser.

Claim 8 required means for collection in the form of "a twin cap, a safety one and another one for collection", but the skilled person would not know how to build means for collection which were closure means. For this reason, the patent in suit did not contain sufficient information to enable a skilled person to carry out the invention as defined in claim 8.

At the oral proceedings before the board, the respondent did not object to the case being remitted to the opposition division for further prosecution.

VII. Oral proceedings before the board of appeal took place on 13 July 2017.

VIII. The final requests of the parties were the following:

- The appellant requested that the decision under appeal be set aside, the case remitted to the opposition division and the appeal fee refunded or, subsidiarily, that the case be remitted for further examination on the basis of the amended main request filed during the oral proceedings before the opposition division.

- The respondent requested that the appeal be dismissed.

IX. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Alleged procedural violation

2. The appellant argued that the impugned decision was not sufficiently reasoned, as it provided a non-exhaustive list of items ("selecting some of the aspects raised...") for which sufficient information was lacking in the patent specification, without explaining why said lack of information would prevent the skilled person from carrying out the invention. The decision further mentioned that the description of the patent in suit was very limited, but did not give reasons why it was limited, and how that might have a bearing on sufficiency of disclosure. Lastly, the opposition division said there were "a great multiplicity of possible implementations", but failed to explain why that was an undue burden for the person skilled in the art trying to reproduce the invention.
3. Point 4.3 of the impugned decision explains that a flow and control scheme was a prerequisite for providing the necessary hard- and software for the claimed invention, from which the division concluded that the skilled person was thus faced with a great multiplicity of possible implementations. From this passage alone, it is possible to understand the chain of thinking of the opposition division, and why it arrived at the

conclusion that the invention as claimed in the main request was not sufficiently disclosed. In this context, it is also relevant that the appellant was able to understand these reasons and to address them by filing the corresponding counter-arguments in its notice of appeal.

4. It is therefore concluded that the decision under appeal is sufficiently reasoned (Rule 111(2) EPC), and thus that no procedural violation took place.

Sufficiency of disclosure

5. According to the case law, the requirements of sufficiency of disclosure are met only if the claimed invention can be performed by a person skilled in the art without undue burden over the whole area claimed, using common general knowledge and having regard to the information in the patent in suit (T 409/91, OJ 1994, 653, Reasons 3.5; T 435/91, OJ 1995, 188, Reasons 2.2.1).

- 5.1 Claim 1 of the main request relates to a cold steriliser for medical devices, in particular for endoscopes, operating with agents effective at 20-35°C, comprising in essence tanks (1) for sterilising chemical agents, removable containers (3) for flexible medical devices and removable casings (7) for rigid medical devices. It is not disputed that sterilisers for flexible endoscopes and sterilisers for rigid endoscopes were state of the art at the filing date.

- 5.2 The respondent argued that there was no disclosure in the patent in suit which could allow the skilled person to identify the means for circulation and for assuring circulation under pressure required by features d) and

e) of claim 1. It argued that the skilled person had no information on how to circulate the chemicals, or on how to control the level of chemicals in the containers. Flexible and rigid endoscopes needed different sterilisation pressures, cycles and times, but none of these variables was disclosed anywhere in the patent in suit.

5.3 The appellant acknowledged that the claimed steriliser combined the features of two well-known types of sterilisers, namely of those for flexible endoscopes and those for rigid endoscopes. It argued that the hydraulic connection between the parts could simply be represented by a parallel connection. This is obviously an embodiment of claim 1, and the board fails to see how the skilled person would face any insoluble problem when trying to implement the design of the circulation paths and the required pumps of the parallel arrangement of two known hydraulic systems. Thus, the skilled person has one way of carrying out the invention available to him.

5.4 The respondent argued that any hydraulic circuit should be carefully planned by an engineer, and that claim 1 also included embodiments which were very complicated, and which the skilled person could not put into practice without using inventive skills. There were also safety concerns involved, which made such design anything but straightforward.

The arguments of the respondent hinge on saying that the skilled person is confronted with many possibilities and little or no guidance. However, the board fails to see embodiments within the ambit of claim 1 which are not feasible, or which are not within the skills of an engineer, in particular as it is not

disputed that every component of the claimed cold steriliser is known from the prior art. The appellant has mentioned very simple embodiments for each of the features described in terms of its function, such as "means for the automatic and safe collection of the chemical agents" (nozzles) "means for circulation" (piping), "means for assuring the circulation under pressure" (pumps), "means for allowing purging" (air stream) or "means for detecting" (sensors). It is evident that the position of the different elements would affect the final performance of the claimed steriliser, but the board fails to see any reason why the position of a sensor within the system - to give just an example - would imply that the invention could not be carried out, or that the skilled person would face insurmountable difficulties in placing it anywhere.

- 5.5 The respondent has further argued that the patent did not disclose how the claimed steriliser could achieve the sterilisation standard set out in paragraph [0004] of the patent in suit, and concluded from that that the claimed invention was insufficiently disclosed.

However, the level of sterilisation is not a feature of claim 1. Whether or not the claimed steriliser could achieve the required sterilisation level is an issue which might need to be examined under inventive step, but which is not an impediment to sufficiency of disclosure, which, in the present case, merely requires that the claimed steriliser can be produced, irrespective of its performance.

For the same reasons, whether the casings (7) depicted in figure 2 of the patent in suit allowed sterilisation of rigid endoscopes to a suitable level is not an issue

under sufficiency of disclosure either.

- 5.6 The respondent also argued that feature c) of claim 1 required means for the automatic and safe collection of chemicals. However, there was no explanation of the meaning of the feature "automatic" in the patent in suit, which only referred in this context to a pierceable seal. For this reason, the skilled person would not be in a position to implement the required means for collection.

However, the board fails to see why the feature "automatic" should represent any limitation over and above meaning that the steriliser has controls which allow chemicals to be collected without human intervention. In addition, it has not been contested that automatic collection means for endoscope sterilisers were state of the art at the filing date.

- 5.7 The respondent argued that feature b) of claim 1 required a room which was or contained a container. However, the patent in suit did not provide information on the embodiment in which the room was a container, in particular as far as connections and joints were concerned.

The board fails to see why it would be difficult for the skilled reader to obtain a steriliser containing a container which can be detached from it, in particular as it is not disputed that such sterilisers were known at the date of filing.

- 5.8 The respondent argued that claim 8 required means for collection "in the form of a twin cap, a safety one and another one for collection". The skilled person would not know how to build means for collection which were

closure means and, for this reason, the claimed invention was not sufficiently disclosed.

However, claim 8 goes on to require that any of these caps has a seal automatically pierceable during the operation of the steriliser. Contrary to the respondent's arguments, caps which can be pierced represent collecting means in the sense of the invention.

- 5.9 The board thus concludes that the subject-matter of claim 1 is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, so the ground under Article 100(b) EPC does not preclude the maintenance of the patent as granted.

Remittal

6. The opposition division revoked the patent in suit due to insufficiency of disclosure, but did not deal with all the grounds for opposition. Under these circumstances, the board considers it appropriate to grant the appellant's request that the case be remitted to the opposition division for further prosecution on the basis of the claims according to the main request (Article 111(1) EPC). The respondent has not objected to remittal.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated