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**Datasheet for the decision
of 8 June 2010**

Case Number: T 0027/07 - 3.2.02

Application Number: 99115093.9

Publication Number: 0978251

IPC: A61B 1/12

Language of the proceedings: EN

Title of invention:

Endoscope capable of being autoclaved

Patentee:

Olympus Corporation

Opponent:

HOYA CORPORATION

Headword:

-

Relevant legal provisions:

EPC Art. 56, 114(2)

RPBA Art. 12(2),(4), 13(1)

Relevant legal provisions (EPC 1973):

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Keyword:

"Inventive step (main and first auxiliary request - no)"

"Second auxiliary request (not admitted)"

Decisions cited:

R 0007/09

Catchword:

-



Case Number: T 0027/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 8 June 2010

Appellant:
(Opponent)

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Decision under appeal:

Decision of the Opposition Division of the
European Patent Office posted 9 November 2006
rejecting the opposition filed against European
patent No. 0978251 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: M. Noël
Members: D. Valle
M. J. Vogel

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal on 2 January 2007 against the decision of the Opposition Division posted on 9 November 2006 rejecting the opposition against European patent No. 0 978 251. The fee for appeal was paid at the same time and the statement setting out the grounds of appeal was received on 19 March 2007.
- II. The Opposition Division held that the claimed subject-matter involved an inventive step over the prior art represented, in particular, by documents:
- D2 = JP - A - 5-253168, and
D3 = DE - A1 - 3 708 124
- III. On 20 February 2009 the Board issued a decision revoking the patent, which was then cancelled on 22 July 2009 by decision of the Enlarged Board of Appeal in case R 7/09. The petition for review was allowed due to a fundamental violation of Article 113 EPC (statement of grounds of appeal never notified to the patent proprietor) and the appeal proceedings before the Board were re-opened.
- IV. On 10 December 2009 the respondent (patent proprietor) replied to the appellant's statement of grounds and filed amended sets of claims according to two auxiliary requests.

V. Oral proceedings were held on 8 June 2010.

The appellant requested that the decision under appeal be set aside and that the European patent be revoked.

The respondent requested that the patent be maintained on the basis of:

- claims 1 to 21 (main request) filed as auxiliary request 1 with letter of 10 December 2009, or
- claims 1 to 20 (first auxiliary request) filed as auxiliary request 2 with letter of 10 December 2009), or
- claims 1 to 5 (second auxiliary request) filed during the oral proceedings.

VI. Claims 1 of each of the various requests reads, respectively, as follows:

Main request:

"An endoscope capable of being autoclaved, comprising: an insertion unit (2) having a soft member (10); an internal endoscope space including the internal space of said insertion unit (2) that is sealed at a first sealing level at which the internal space is sealed in a watertight manner relative to an outside; and contents (17, 31; 337, 358) all or part of which are arranged in said internal endoscope space; wherein said contents (17, 31; 337, 358) include at least one hermetically sealed unit (38, 39; 337, 358) composed of a plurality of airtight partition members (36, 37; 39, 41, 44, 47; 339, 338, 340; 360, 359, 361) and formed at a second sealing level higher than the

first sealing level by joining the sealing surfaces of said airtight partition members using an airtight joining means (61 - 65);

wherein even when high-pressure high-temperature steam permeates through said soft member (10) of said insertion unit (2) which is made of a soft polymeric material as at least part of an insertion unit casing, and invades into said internal endoscope space formed at the first sealing level, the high-pressure high-temperature steam will be hindered from invading into the hermetically sealed unit (38, 39, 337, 358) included in said contents and formed at the second sealing level; and

wherein said hermetically sealed unit (38, 39; 337, 358) includes at least one of optical members (38, 44-47; 341; 362) and electronic parts (43) or both the optical members and electronic parts."

First auxiliary request:

Claim 1 of the first auxiliary request contains all the features of claim 1 of the main request and the following feature added at the end of the claim:

"and wherein said hermetically sealed unit (38, 39; 337, 358) includes as optical members a lens unit (38, 341, 362) and said airtight partition members (36, 37; 39, 41, 44, 47; 339, 338, 340; 360, 359, 361), hermetically locked as optical windows (36, 44; 339, 340; 360, 361) in both end portions thereof."

Second auxiliary request:

"An endoscope capable of being autoclaved, comprising: an insertion unit (2) having a soft member (10); an internal endoscope space including the internal space of said insertion unit (2) that is sealed at a first sealing level at which the internal space is sealed in a watertight manner relative to an outside; and contents (17, 31; 337, 358) all or part of which are arranged in said internal endoscope space; wherein said contents (17, 31; 337, 358) include at least one hermetically sealed unit (38, 39; 337; 358) composed of a plurality of airtight partition members (36, 37; 39, 41; 44,47; 339, 338, 340; 360, 359, 361) and formed at a second sealing level higher than the first sealing level by joining the sealing surfaces of said airtight partition members using an airtight joining means (61-65); wherein even when high-pressure high-temperature steam permeates through said soft member (10) of said insertion unit (2) which is made of a soft polymeric material as at least part of a insertion unit casing, and invades into said internal endoscope space formed at the first sealing level, the high-pressure high-temperature steam will be hindered from invading into the hermetically sealed unit (38, 39, 337, 358) included in said contents and formed at the second sealing level; wherein said hermetically sealed unit (38, 39; 337; 358) includes optical members and electronic parts; wherein said hermetically sealed unit (38, 39; 337; 358) is part of an observing means (17), said hermetically sealed unit including a first optical window (36, 360, 339) hermetically locked therein, said optical window is one of said airtight partition members and bared on the outer surface of said

endoscope (1) as part of the housing thereof wherein said observing means (17) is an imaging unit having a solid-state imaging device (43) as part of an image transmitting means, and said optical members include an objective unit (38) having a second hermetically locked optical window (44) located at the image input end of said solid-state imaging device (43)."

VII. The appellant argued essentially as follows:

The subject-matter of claim 1 of the main request did not imply an inventive step in consideration of the teaching of D3 and the general knowledge of the skilled person. D3 disclosed a flexible insertion portion 152. As acknowledged in the patent in suit (see in particular paragraph [10]), it was known at the filing date of the patent that endoscopes might have an armor tube made of a soft polymeric material such as rubber or elastomer. In D2, too, a soft rubber tube was used to cover the bending portion 4 of the endoscope. Furthermore, in D3 steam entering the interior of the endoscope was not excluded, despite high airtight sealing levels (see column 18, lines 53-56). D3, therefore, achieved the same two-sealing-level protection as in the contested patent, and the problem of scaling down the airtight protection relative to the outside to a mere watertight protection as required by the invention was artificial. The solution, if any, did not provide any inventive contribution to the problem since the selection of a lower sealing level for the outer flexible tube had no technical effect on the airtight sealing of the internal partition members.

The additional features incorporated in claim 1 of the first auxiliary request were also known from D3 and did not have any inventive significance. In particular, the provision of optical windows at both ends of the hermetically sealed unit represented a trivial constructional measure.

The second auxiliary request was filed belatedly, at the end of the oral proceedings, and, if only for this reason, should not be admitted into the present appeal proceedings.

VIII. The respondent argued essentially as follows:

The endoscope proposed in D3 was entirely airtight and thus led the person skilled in the art away from the claimed endoscope with two different sealing levels. According to D3 (see column 3, lines 32 to 37) the problem of avoiding the optical unit being fogged was already solved by the use of a hygroscopic material. Therefore there was no need to lower the airtight sealing level of the outside parts of the endoscope to a watertight sealing level. There was also no reason to do it since lowering the sealing level of the endoscope as a whole would correspond to lesser protection, i.e. no better protection than conventional endoscopes. In the patent in suit the use of soft polymeric material was wrongly acknowledged as known. The assumption that this material was generally known was based on an internal subjective statement of the applicant. Besides, there was no evidence that this material was previously used for making the insertion portion of endoscopes.

The features added in claim 1 of the first auxiliary request reinforced the contribution to the inventive step of the solution. The provision of optical windows guaranteed that the whole optical unit was locked between a pair of separate cover glasses, in contrast to Figure 30 of D3, where the presence of a fibre bundle 166 prevented hermetically sealing the optical unit on the proximal end thereof. An optical window was not similar to a lens, and claim 1 clearly required that the optical lens unit as such be hermetically locked, as mentioned in particular in paragraphs [61] and [102] of the patent in suit. Moreover, as shown in Figures 9 and 10 of the patent, the space between the elements of the sealed unit allowed for adjusting and focusing the group of objectives, which was not permitted in D3 due to constructional differences.

The late filing of the second auxiliary request was justified by the fact that the situation had substantially changed following the discussion of the first auxiliary request during the oral proceedings. Claim 1 of the second auxiliary request was a combination of granted claims and, therefore, could not come as a surprise for the other party.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

The admissibility of the amendments made to the subject-matter of claim 1 of the main request and of

the first auxiliary request with respect to the version of claim 1 as granted need not be answered, since these requests are not allowable for other reasons, as demonstrated hereinafter.

3. *Inventive step*

3.1 Interpretation of claim 1

In claim 1 of each request, the feature relating to contents including at least one hermetically sealed unit composed of a plurality of airtight partition members and formed at a second sealing level higher than the first sealing level is understood as actually referring to the hermetically sealed unit formed e.g. by the imaging unit 17 shown in Figure 4 or the objective unit 40 shown in Figure 10 and comprising a plurality of airtight partition members such as, in particular, a first cover glass 36, a distal frame 37, a lens frame 39, a group of objectives 38, an isolating frame 41, a metallic frame 47 and a second cover glass 44, all sealed in an airtight manner with respect to each other and to the outside of said unit (see patent, paragraphs [40] and [103]).

3.2 Main request

D3 (see Figure 29) discloses an endoscope capable of being autoclaved (sterilized, see column 3, lines 12-14), comprising an insertion unit (152, 156, 157) having a soft and flexible member (see column 18, lines 1-2); and an internal endoscope space including the internal space of said insertion unit that is sealed in an airtight manner relative to the outside.

As a matter of fact, the flexible endoscope as a whole is sealed in an airtight manner (see column 18, lines 6-7).

Further, D3 discloses (Figure 30) contents (155, 162-164, 168) arranged within said internal endoscope space, including at least one hermetically sealed unit composed of a plurality of airtight partition members sealed by joining the meeting portions of said airtight partition members using airtight joining means (175 to 178), so that even when high-pressure high-temperature steam given off during autoclaving permeates through said soft member of said insertion unit and invades into said internal endoscope space, the high-pressure high-temperature steam will be hindered from invading into the hermetically sealed unit included in said contents, wherein said hermetically sealed unit includes optical members (see column 18, lines 37-56).

With respect to this latter feature (optical members) it is observed that the last feature of claim 1 at issue is worded so as to include a number of alternatives introduced by the words "at least one of" and "or". Therefore, it is permissible to consider only the optical members and to ignore the other combinations of components for the comparison with the state of the art.

However, D3 does not disclose the feature of claim 1 in suit according to which the soft member of the insertion unit is made of a soft polymeric material and that the internal space of the insertion unit is sealed relative to the outside in a watertight manner at a first sealing level, whereas the hermetically sealed

unit is sealed in an airtight manner, i.e. at a second sealing level higher than the first watertight sealing level.

The technical problem presented in the contested patent (see paragraphs [35] to [38]) of providing an endoscope capable of avoiding high-pressure high-temperature steam invading into the interior of the endoscope and the optical system during autoclaving has already been addressed in D3 (see column 3, lines 4-12 and 32-37). It is solved in this document by the provision of an endoscope entirely sealed in an airtight manner (see column 18, lines 1-7).

However, even if the outside fitting parts of the endoscope are made airtight, there is still a risk of high-pressure high-temperature steam entering the interior of the endoscope during sterilisation (see column 3, lines 4-17 and column 18, lines 52-56). If the device of D3 was really entirely airtight, as it is supposed to be, the above-mentioned risk would not be present any more. Therefore, it is likely that the outer tube 152, 157 shown in Figures 29 and 30 might only be watertight, as is generally the case in conventional endoscopes.

Moreover, as explained in the patent itself (see paragraphs [19] and [21], for endoscopes known as airtight endoscopes and having a bending ability (as in the case in D3), the steam given off during autoclaving can barely be prevented from invading into the interior of the endoscope.

Furthermore, it is well known from the state of the art presented in the application itself that conventional endoscopes have a soft, bendable insertion unit comprising a tube made of soft polymeric material, thus providing a watertight sealing level (see patent, paragraphs [10], [17], [20] and [31]). Additionally, D2 (see paragraph [9] of the English translation) discloses an example of rubber used as a suitable material for the bending portion, as recited in paragraph [10] of the contested patent concerning the soft polymeric material.

Starting from the disclosure of D3, even if it is assumed that the outer tubes 152, 157 are such as to provide an airtight sealing level, the skilled person would indeed consider lowering this level to a still acceptable watertight sealing level, on the basis of his common general knowledge as given in the application as filed, the more so since lowering the sealing level of the internal space of the insertion unit from airtight to watertight has no bearing on the level of protection of the internal hermetically sealed unit, which remains airtight anyway. In fact, the plurality of airtight partition members such as optical members and electronic parts are all formed at a higher airtight sealing level and are sufficiently protected against high-pressure high-temperature steam entering the interior of the endoscope during autoclaving.

It is true that, as submitted by the respondent, common general knowledge needs to be substantiated if challenged by a party. In the present case, however, the information emerges from the applicant himself in the application as originally filed. It is not the

responsibility of the Board or the other party to provide evidence whether the state of the art presented in the application as filed, now no longer acknowledged by the respondent-proprietor, is correct or not. On the contrary, it is the proprietor's responsibility to provide the EPO with a text ready for grant, i.e. agreed by him (Article 113(2) EPC).

It results therefrom that the subject-matter of claim 1 of the main request does not involve an inventive step within the meaning of Article 56 EPC with respect to the disclosure of D3, having regards to the general knowledge of the person skilled in the art.

3.3 First auxiliary request

The additional feature of claim 1 of the first auxiliary request is also disclosed by D3. Like the present patent, D3 (see Figure 30) discloses a hermetically sealed unit including an optical lens unit 155 and airtight partition members (162-164, 168, 175, 178), hermetically locked by an optical window 162 at the distal end thereof. D3 does not disclose a separate optical window at the proximal end of the hermetically sealed unit (comparable to the cover glass 44 in the patent). However, the most proximal lens of the objective system 155 of D3 is able to play this role, given that airtight sealing of the whole optical unit is warranted by means of airtight joints 177, 178 provided between a spacer 168 and a lens frame 164.

Moreover, there is no indication from the description of the present patent that the optical window 44 at the proximal end of the sealed unit is of particular

relevance to the invention, so that the proximal window appears as a mere counterpart or duplication of the distal window, without special significance.

The respondent's argument in relation to Figures 9 and 10 of the patent in suit that the space between the group of objectives 38 and the group of lenses 46 adjacent to the cover glass 46 allows for adjusting the focusing of the optical system, is not supported by the description and is, therefore, irrelevant. Figure 9 is an exploded view illustrating the method of assembling the components of the objective unit 40, all firmly secured after assembling. A relative movement of these components with respect to each other is not provided. Once the lens frame 39 is adjusted to bring the group of objectives into focus, the lens frame is securely fixed to the isolating frame 41 (see patent, paragraph [99]).

Accordingly, the subject-matter of claim 1 of the first auxiliary request does not involve an inventive step.

4. Second auxiliary request - admissibility

The set of claims according to the second auxiliary request was filed at the end of the oral proceedings. Claim 1 incorporates subject-matter from claims 6, 8 and 9 as granted, of which claims 6 and 9 are a modified version.

This new combination of features was never considered before by the first instance, the appellant or the Board and gives rise to new, formally and substantively objectionable subject-matter, so that it would normally

necessitate remittal of the case for further prosecution. However, remittal of the case is excluded at this stage of the proceedings for reasons of equity and procedural economy.

Therefore, the Board using the discretion conferred on it by Article 13(1) RPBA, decided not to admit this auxiliary request which, according to Article 12(4) RPBA, could have been filed by the respondent at an earlier stage either before the first instance or at the latest before the Board, preferably with the respondent's reply of 10 December 2009 to the statement of grounds of the appellant. In the present situation, the Board was clearly confronted with an incomplete case from the relevant party, contrary to the provisions of Article 12(2) RPBA.

Therefore, the second auxiliary request is not admitted into the appeal proceedings under Article 114(2) EPC

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

D. Sauter

M. Noël