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Datasheet for the decision of 18 May 2010

Case Number:	T 0030/08 - 3.2.02				
Application Number:	01962510.2				
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IPC:	A61B 1/267				
Language of the proceedings:	EN				
Title of invention: Intubation Instrument					
Patentee: Verathon Medical (Canada) ULC					
Opponent: Aircraft Medical Limited					
Headword: -					
Relevant legal provisions: EPC Art. 123(2), 56					
Relevant legal provisions (EPC 1973):					
Keyword: "Extended subject-matter (no)" "Inventive step (yes, after amendments)"					
Decisions cited:					
Catchword:					

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Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 0030/08 - 3.2.02

DECISION of the Technical Board of Appeal 3.2.02 of 18 May 2010

Appellant I: (Patent Proprietor)	Verathon Medical (Canada) ULC Suite 900, Purdy's Wharf Tower One 1959 Upper Water Street Halifax, NS B3J 2X2 (CA)
Representative:	Carter, Stephen John Mewburn Ellis LLP 33 Gutter Lane London EC2V 8AS (GB)
Appellant II: (Opponent)	Aircraft Medical Limited 10 St. Andrews Square Edinburgh EH2 2AF (GB)
Representative:	Hindle, Alistair Andrew Hindle Lowther 66 Hanover Street Edinburgh EH2 1EL (GB)
Decision under appeal:	Interlocutory decision of the Opposition Division of the European Patent Office posted 30 October 2007 concerning maintenance of European patent No. 1307131 in amended form.

Composition of the Board:

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

Summary of Facts and Submissions

I. The appellant I (patentee) lodged an appeal on 8 January 2008 against the interlocutory decision of the Opposition Division posted on 30 October 2007 to maintain the patent in amended form. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 7 March 2008, along with amended claims according to eleven auxiliary requests.

> Subsequent to the communications of the Board dated 16 February 2010 and 13 April 2010, respectively, appellant I filed with letter of 16 April 2010 amended sets of claims according to a main request and nine auxiliary requests.

- II. The appellant II (opponent) lodged an appeal on 27 December 2007 against the above decision and paid the fee for appeal simultaneously. The statement setting out the grounds for appeal was received on 8 March 2008. A further reply was submitted by appellant II with letter of 16 April 2010.
- III. The following documents have been considered for the present decision:

D1: GB - A - 2 086 732
D3: US - A - 5 800 344
D5: US - A - 5 827 178
D10: W0 - A1 - 99/27840.
Annexes A to F filed with the patentee's letter of
23 July 2008

Annexes 1 to 5 and the video-tape filed with the patentee's letter of 16 April 2010.

IV. Oral proceedings took place on 18 May 2010.

The appellant I (patentee) requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the main request or one of the auxiliary requests 1 to 9, all filed with letter of 16 April 2010.

The appellant II (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

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

"An intubation instrument, a portion of which is for insertion into a patient through the patient's mouth, comprising: a body (20', 20") having a handle (24) attached thereto; an elongate arm (22) having substantially straight elongate base portion (202) attached to the body (20', 20") and a substantially straight elongate lifter portion (204) extending from said elongate base portion (202) at a defined angle (208), said elongate base portion (202) having a first defined length (207), said elongate lifter portion (204) having a second defined length (205) and a smooth surface for engaging the patient's epiglottis and a distal end (210) for insertion distal-end first through a patient's mouth, said elongate arm (22) defining an anterior side positioned toward said handle and an opposite posterior side, and a viewer (80') operably secured to said posterior side of said arm (22)

substantially where said elongate base portion (202) meets said elongate lifter portion (204); characterized in that said second defined length (205) being about as long as first defined length (207); said viewer (80') being directed toward the distal end (210) of said elongate lifter portion (204); and said viewer (80') being a camera."

VI. The appellant I (patentee) argued essentially as follows:

The position of the viewer and as a consequence of the camera was sufficiently supported by the original disclosure, especially by the term "meets" to be found in claims 2, 20 and 25 and by the drawings of the application as filed.

D1 disclosed originally a direct laryngoscope, then modified by the addition of a prism which had been used very rarely. Figure 17 was misleading in the sense that the instrument was in fact introduced laterally in the corner of the mouth and bent in order to avoid the teeth, see in this respect the documents in Annex 4. On the contrary, the device according to the invention was of the indirect type, that is having an indirect line of sight from the outside of the patient's mouth and in which the bend was provided for placing the camera in an appropriate direction.

D5 also disclosed a direct laryngoscope, however with a camera being placed unprotected near the tip at the distal end of the blade, contrary to the invention where the camera is placed as far away from the distal end as possible. D3 showed a camera placed tangentially at the elbow of a convex blade, however this document was not clear about the reasons for positioning the camera away from the distal end of the blade. The curved distal end had principally the purpose of avoiding the tissue interfering with the camera, not to improve the field of view towards the contacting point.

D10 did not disclose the position and the direction of the viewer as claimed. The loop 60 was angled and sized to match the diameter and curvature of the endotracheal tube, but not comparable with the claimed lifter portion, the purpose of which was to space the camera away from the distal end of the lifter portion.

The gist of the invention lay in the particular position and orientation of the camera midway down the blade, which configuration provided a greater field of view along the lifter portion and facilitated navigation of the tracheal tube towards the right opening.

The invention had been particularly successful on the market since it could provide grade 1 clarity of view (the maximum grade quality).

VII. The appellant II (opponent) argued essentially as follows:

Claim 1 of the main request contained added subjectmatter. The feature according to which "a viewer (80') operably secured ... substantially where said elongate base portion (202) meets said elongate lifter portion" was not originally disclosed as such. The correct formulation should specify that the viewer was positioned in the vicinity of the area, as recited in claims 2, 20 and 25 of the application as filed.

The subject-matter of claim 1 of the main request did not involve an inventive step in view of a combination of the teaching of D1 with that of D3 or D10 or, alternatively, starting from D10 in combination with D1, having regard to D3.

Starting from D1, which only differed from claim 1 by the provision of a camera in the alleged invention, the objective problem underlying the invention was to provide an alternative viewing means. The problem defined in paragraph [12] of the patent did not consider the teaching of D1 and, therefore, was not appropriate.

D3 disclosed a camera placed at the elbow of a curved blade and spaced apart from its tip. Moreover, the camera was made adjustable in position along tracks. Therefore it was obvious to replace the prism of D1 with the camera of D3 and to position the camera at the junction between the base portion and the lifter portion disclosed in D1. D10 too disclosed the use of a camera and a lifter portion in the form of a loop, the length of which could have been extended according to need.

Starting from D10, which disclosed (see Figure 6) an inclined portion (loop) having a length a bit shorter than the lifter portion according to the invention and a telescope provided with a lens 82 at its distal end or a camera, D1 suggested to the person skilled in the art to refract the ray of light towards the lifter portion and the glottis. The subject-matter of claim 1, therefore, did not imply an inventive step having regard to the combination of the teachings of D10 and D1.

There was no clear evidence of the commercial success of the marketed device of the invention. The evidence filed by the appellant I to support this was not convincing, the more so since commercial success was only a weak indication of inventive step.

The arguments of the appellant I regarding the different types of laryngoscopes (direct or indirect) or regarding the intubation method used were irrelevant, since the patent in suit was silent in these respects. In particular, the sniffing position referred to in paragraph [23] of the patent did not constitute an advantage. The relevant point was the invention as described in the patent, not what the appellant I interpreted by an extensive reading of the claimed subject-matter.

Regarding the clarity of view (grade), the patent in suit was silent on this mater and the results achieved by the laryngoscope according to the invention were no better than those obtained from the laryngoscope according to D1. Both devices gave rise to failures, as reported in Annex 4.

Reasons for the Decision

- 1. The appeals are admissible.
- 2. Late filed submissions
- 2.1 With letter of 16 April 2010 the appellant I filed new sets of claims comprising a main request and nine auxiliary requests, in response to the communications of the Board and to the arguments provided by the appellant II. Since at the oral proceedings the appellant II did not contest the admissibility of these new requests and since the Board too saw no reason to contest them despite their late-filing, the new requests were admitted into the proceedings.
- 2.2 At the oral proceedings, the admissibility of documents D6 (US-A-5443058), D8 ("A mirror laryngoscope" by Siker E.S. from "The world knowledge", Vol. 17, Jan. 1956, pp 38-42) and D11 (US-A-4086919) was discussed. However, this matter can be left aside since these documents are not relevant for the present decision.

The other documents and annexes introduced by the parties after the filing of their statements of grounds, such as various declarations, journal articles, a video-tape, excerpts from expert reports submitted in proceedings before other courts, are admitted into the present appeal proceedings as further evidence with a view to better understanding and assessment of the invention and of the prior art documents. The consideration of these pieces of evidence is not precluded by the European Patent Convention and is at the Board's discretion. In this respect it should be observed that the Board is independent and not bound by the reasoning of any national court, even if the Board might arrive at a similar conclusion. However, where useful, some pieces of evidence provided before a national court may be admitted by the Board into its own proceedings.

3. Amendments - main request

With respect to the version as granted, the subjectmatter of claim 1 according to the main request differs by the addition of the last characterising feature: "said viewer (80') being a camera". This limiting feature is fairly supported by the application as filed (see page 16, line 18) and illustrated in Figures 7 to 11B which represent various embodiments of the invention. The requirements of Article 123(2) EPC are therefore met.

The Board does not accept the objection of the appellant II that the expression "in the vicinity of the area" should be incorporated into claim 1 to more closely specify the position of the viewer in accordance with the definition of the invention presented in the application as filed.

As a matter of fact, the expression "a viewer positioned **in the vicinity of the area where** the base portion meets the lifter portion of the arm" appears for the first time in dependent claim 2 as originally filed, and is actually broader than the currently claimed feature: "a viewer operably secured to said posterior side of said arm **where** said elongate base portion meets said elongate lifter portion". Therefore, the subject-matter of claim 1 does not extend beyond the content of the application as filed, in compliance with Article 123(2) EPC.

Moreover, the objection of the appellant II relating to the position of the viewer does not concern the feature added to claim 1 with respect to the version as granted i.e. the amendment itself ("said viewer being the camera"). The objection of the appellant II is, therefore, irrelevant.

4. Inventive step - main request

At the oral proceedings, the inventive step of claim 1 was objected to by the appellant II, starting from either D1 or D10 taken as the closest prior art document. The Board will consider these two lines of argument, successively.

- 4.1 D1 as closest prior art
- 4.1.1 According to the wording of claim 1 in suit, D1 discloses an intubation instrument, a portion of which is for insertion into a patient through the patient's mouth (see Figure 9), comprising a body having a handle 43 attached thereto (see page 2, lines 22 to 26), an elongate arm having a substantially straight elongate base portion 24A, 27 attached to the body and a substantially straight elongate lifter portion 24B, 28 extending from said elongate base portion at a defined angle, said elongate base portion having a first defined length, said elongate lifter portion having a second defined length and a smooth surface for engaging the patient's epiglottis and a distal end for insertion

distal-end first through a patient's mouth, said elongate arm defining an anterior side positioned toward said handle and an opposite posterior side, and a viewer (i.e. a viewing device embodied in D1 by the optic prism 10) operably mounted into said posterior side of the first defined length of said arm; whereby said second defined length is about as long as first defined length (see in particular Figure 7 and page 3, line 129 to page 4 line 6). In D1, the viewer is arranged so as to visualise an area around the distal end of the elongate lifter portion (see Figures 9 and 17 and the text referred to).

However, D1 does not disclose that the viewer is "secured" where said elongate base portion meets said elongate lifter portion, that the viewer is directed (i.e. oriented) toward the distal end of said elongate lifter portion, and that the viewer is a camera.

These distinguishing features over D1 represent the solution to the relevant technical problem identified in paragraph [12] of the contested patent, namely to provide an intubation device that includes a configuration and arrangement of components that greatly facilitate rapid, safe placement of the instrument. More specifically, the claimed combination allows for further enhancing the viewing of the advancing tube at the introduction site, while providing the user with a clear perspective view of the entire area (see paragraph [49] of the patent).

In D1, the prism 10 is accommodated principally within the straight elongate base portion, with the end surface 11 of the prism protruding where the base portion meets the elongate lifter portion (see Figures 8 and 9). In the Board's view, this assembly is not similar to a viewer entirely positioned and secured at said meeting point as required by the wording of claim 1.

It matters little that in D1 the ray of light 38, 39 is refracted through the face 11 of the prism in the direction of the target. What counts is the prism itself taken as a component of the laryngoscope, which is directed differently from the orientation of the camera of the present invention. In claim 1 at issue the viewer (camera) is defined both by its position and its direction. Besides being positioned and secured where the base portion meets the lifter portion, the camera is additionally directed towards the distal end of the lifter portion, in order to create a greater field of view of the relevant area of work and to facilitate intubation into the correct opening of the body. This combination of features is, however, not disclosed or suggested by the teaching of D1.

4.1.2 D3 discloses (see Figures 1 to 3) a video laryngoscope comprising a body 12 including a main curved base portion and a more convex end portion (elbow 34) forming a lifter portion, and a viewer (sensor assembly 40, 42) placed at the junction between the base portion and the lifter portion. The distal tip 18 of the lifter portion is adapted to urge the tissue to be contacted in a desired direction (see column 3, lines 17-21) so as to provide a better view of the area of interest.

However, the image sensor assembly or camera 40 is mounted at the distal end of the base portion and

directed tangentially with respect to the more convex portion 30, such that the viewer is not directed towards the distal end of the lifter portion but away from it, i.e. away from the contacted tissue and the region of interest (see column 3, lines 28-34). This teaching is going in the opposite direction to the claimed subject-matter.

The alternative embodiment presented in Figure 4 of D3 does not change the previous findings of the Board, since the rails 58 for moving the image sensor assembly are interrupted somewhere before the distal end of the curved blade. Therefore, even if the angle of orientation of the image sensor is varied when the sensor assembly is moved along the rails, the viewer still cannot be directed towards the distal end of the lifter portion.

It results therefrom that even when combining the teachings of D1 and D3 the skilled person would not arrive at the subject-matter of claim 1.

4.1.3 D10 is the prior art from which the present patent emerges. This document originates from the same inventor (J. Pacey) and Figures 1 to 6 of D10 are identical to Figures 1 to 6 of the present patent. This is confirmed in the patent itself (see paragraph [21]) where it is stated that Figures 1 to 6 are not in accordance with the invention, which is rather an improvement illustrated by the embodiments shown in Figures 7 to 11. A detailed acknowledgement of the content of D10 is given in paragraphs [21] to [46] of the contested patent.

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In D10 the intubation instrument 20 includes a body comprising an elongate arm 22 and a loop 60 protruding from the distal end of the arm at an angle of about 45°. The loop is provided principally for guiding an endotracheal tube 40. Further, a viewer in the form of a telescope 80 is introduced through the arm and terminates in a lens and its end 82. As specified on page 12, lines 10-12, the telescope can be replaced by a video camera.

The particulars of the instrument disclosed in D10 are that the lens (or camera) is situated in a clearing 100 (Figure 6) free of view-obstructing tissue, formed by a space between the loop 60 and a guard 70 at the distal end of the arm, and that the leading edge 38 of the tube remains substantially in the field of view of the telescope. However, the protruding loop 60 cannot be regarded as an elongate lifter portion within the meaning of the present invention, i.e. specifically sized so as to more effectively hold the epiqlottis and the surrounding tissue. Although according to an alternative embodiment of D10 (see paragraph bridging pages 9 and 10) it is suggested that the lens may be angled upwardly so that the movement of the tube may be nearly parallel to the centre of view of the telescope, it remains that the viewer is to be directed towards the glottis 36 and not towards the distal end of the loop. Moreover, the means for achieving this change of angulation are not disclosed.

Therefore, in the Board's view, the disclosure of D10 does not suggest directing a camera precisely towards the distal end of an elongated lifter portion of the arm, in order to provide the user with a clear perspective view of the area of interest.

- 4.1.4 D5 discloses a camera mounted unprotected on a blade, at the vicinity of its distal end. But, clearly, the instrument has no lifter portion, so that it is not appropriate to solve the problem defined above. Besides, at the oral proceedings, this document was not further discussed by the appellant II.
- 4.1.5 It results therefrom that the subject-matter of claim 1 of the main request involves an inventive step starting from the teaching of D1 in combination with one of D3, D10 or D5.
- 4.2 D10 as closest prior art

According to the wording of claim 1 in suit and taking account of the previous analysis of this document, D10, see in particular Figures 1 and 7, discloses an intubation instrument, a portion of which is for insertion into a patient's mouth, comprising a body 20 having a handle 24 attached thereto; an elongate arm having a substantially straight elongate base portion 22 attached to the body and a substantially straight elongate loop portion 60 extending from said elongate base portion at a defined angle, said elongate base portion having a first defined length, said elongate loop portion having a second defined length and a smooth surface 68 for engaging the patient's epiglottis and a distal end for insertion distal-end first through a patient's mouth, said elongate arm defining an anterior side positioned toward said handle and an opposite posterior side, and a viewer 82 operably

secured to said posterior side of said arm substantially where said elongate base portion meets said elongate loop portion; said viewer being a camera.

However, D10 does not disclose that the second defined length is about as long as the first defined length. On the contrary, the length of the base portion is remarkably bigger than the length of the protruding loop portion. Moreover, the viewer is not directed towards the distal end of the angled loop, but at best towards the glottis, as mentioned above (point 4.1.3).

The purpose of the invention is therefore to be seen in providing a better view of the intubation area and, as before, to facilitate rapid and safe placement of the instrument, as recited in paragraph [12] of the patent in suit. The distinguishing features of the invention also provide for the camera being still better protected from view-obstructing tissue and debris due to an enlarged space under the lifter portion.

Contrary to the assertion of appellant II, the embodiment referred to at the bottom of page 13 of D10 in relation to Figures 7 and 8 does not suggest a base portion and a lifter portion having the same length, as clearly shown in these figures.

D1 discloses, as mentioned above (point 4.1.1), a laryngoscope having a base portion and a lifter portion of about equal length. However, because of the use of a prism, this document is concerned with an indirect or a modified direct laryngoscope, i.e. of a type which is hardly compatible with a direct line-of-sight laryngoscope, such as D10, which is using a straight telescope. Therefore the person skilled in the art would not be prompted to combine these documents. Moreover, as previously explained, D1 fails to disclose a viewer component directed towards the distal end of the elongate lifter portion. As a consequence, even if the skilled person were to combine D10 and D1, he would not arrive at the subject-matter of claim 1 at issue. The subject-matter of claim 1 therefore involves an inventive step.

A further consideration of D3 could not change this view, for the reasons already explained in point 4.1.2 above. Moreover, although the provision of a camera movable along tracks allows for adjusting the view field of the image sensor, D3 as well as D10 belong to that type of laryngoscope where the length of the lifter portion is remarkably shorter than the length of the base portion. This type of instrument requires that, during intubation, the practitioner brings the patient's head into the so-called sniffing position, usually by pulling the patient's head back to elevate the patient's chin in an effort to provide a straight path for receiving the laryngoscope, see patent in suit, paragraphs [9] and [23]. The instrument of the invention, on the other hand, by means of its distinguishing features over D10, allows for insertion without manipulation of the patient's head, thereby greatly facilitating the work of the practitioner. Also for this reason, the Board is of the view that a combination of D10 with D3 does not deprive the subject-matter of claim 1 of the main request of the required inventive step.

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 in amended form in the following version:
 - claims 1 to 17 of the main request filed with letter of 16 April 2010;
 - description and Figures 1 to 11B as granted.

The Registrar:

The Chairman:

D. Sauter

M. Noël