BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

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

Datasheet for the decision of 30 June 2009

Case Number: T 1716/07 - 3.2.02

Application Number: 97915949.8

Publication Number: 0891156

IPC: A61B 17/34

Language of the proceedings: EN

Title of invention:
Device for percutaneous surgery

Patentee:
SDGI Holdings, Inc.

Opponent:
Rudolf Medizintechnik GmbH & Co. KG

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54, 56, 123(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Added subject-matter (no)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1716/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 30 June 2009

Appellant: (Opponent)
Rudolf Medizintechnik GmbH & Co.KG
Zollerstrasse 1
D-78567 Fridingen (DE)

Representative:
Weiss, Peter
Dr. Weiss & Arat
Zeppelinstrasse 4
D-78234 Engen (DE)

Respondent: (Patent Proprietor)
SDGI Holdings, Inc.
300 Delaware Avenue, Suite 508
Wilmington, DE 19801 (US)

Representative:
Every, David Aidan
Marks & Clerk LLP
Sussex House
83-85 Mosley Street
Manchester M2 3LG (GB)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 10 August 2007 rejecting the opposition filed against European patent No. 0891156 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: M. Noel
Members: S. Chowdhury
J. Geschwind

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the interlocutory decision of the opposition division relating to European patent No. 0 891 156.

II. The decision was dispatched on 10 August 2007. The appeal was received on 4 October 2007 and the fee for the appeal was paid on the same day. The statement setting out the grounds of appeal was received on 5 November 2007.

III. The opposition was filed against the whole patent and based on Article 100 (a) and (c) EPC 1973. The opposition division decided that the claims of the patent as granted met the requirements Article 123 (2) EPC and Article 52 (1) EPC and rejected the opposition, accordingly.

IV. The following documents were cited in the appeal procedure:

E1: US-A-5 395 317
E2: DE-C-3 319 049.

V. Oral proceedings before the Board were held on 30 June 2009.

The appellant requested that the decision under appeal be set aside and that European patent No. 0 891 156 be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed (main request) or that the patent

be maintained in amended form according to one of the auxiliary requests 1A, 1B, 2, 2A, 2B, 3, 3A, 3B, or 4 filed by letter dated 2 June 2009.

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

"A device suitable for use in percutaneous surgery without a fluid-maintained working space comprising: an elongated cannula (20) having an inner dimension (D_1) and an outer dimension (D_0) sized for percutaneous introduction into a patient, said cannula (20) having a distal working end and an opposite proximal end (22) and defining a working channel (25) between said ends, said working channel (25) being sized to receive a tool therethrough; a viewing element (50) having a first end (51) connectable to viewing apparatus and an opposite second end (52) disposed adjacent said distal working end of said cannula (20); a fixture (30; 170) removably mounted to said cannula (20) and defining an optics bore (60; 180) adjacent to said working channel (25) for receiving a portion of the viewing element 50 therein such that said viewing element is movable relative to said cannula (20) during surgery, said fixture (30; 170) being arranged such that when it is mounted to said cannula the working channel (25) is open at the proximal end of the cannula (20)".

Claim 43 is to a kit suitable for performing a surgical procedure and comprising a device as in claim 1, and claims 2 to 42 and 44 to 58 are dependent claims.

VII. The parties argued as follows:

Appellant

Original claim 8 related to a device for use in percutaneous spinal surgery whereas granted claim 1 related to a device suitable for percutaneous surgery, which made the claim unjustifiably broader in two respects. The last two features of original claim 8, according to which the optics bore was sized to removably receive the viewing device, and the fixture supported the viewing device for movement within the optics bore along the longitudinal axis of the bore to extend or retract the lens, were also unjustifiably omitted from granted claim 1.

Claim 1 without the following features was not supported by the application as originally filed: a working channel having a second dimension substantially equal to said first inner dimension, a viewing element mounted inside said cannula adjacent said working channel, and a viewing device with a lens.

The provisional opinion of the Board, that E1 disclosed a device suitable for use in percutaneous surgery without a fluid-maintained working space and comprising all the features of claim 1 was correct so that E1 was a novelty destroying document.

E2 also disclosed a device suitable for use in percutaneous surgery since the device of E2 could be inserted into the body through an incision in the skin. There was no indication in the patent in suit of the size of the claimed device. Despite the provision of gas the device of E2 was operable without a fluid-maintained working space, and since it comprised all

the features of claim 1 E2 was also a novelty destroying document.

The person skilled in the art was a surgical mechanic who would be aware of both documents E1 and E2 since they were in related fields of surgery. The skilled person would realise that both devices could be used without a fluid-maintained working space. The patent in suit stated that only a movable viewing device was necessary for this property, and both E1 and E2 had a movable viewing device.

E2 by itself led to the conclusion of lack of inventive step since the skilled person merely needed to leave out the gas seal and use the device without a gas.

The device of E1 had two separate channels, but it would be obvious, given the teaching of E2, to provide a common channel for the viewing device and the surgical instruments.

Respondent

The test for added subject-matter did not involve a comparison with the closest claim originally filed, it was whether the application as a whole had been amended to include added matter. By this test the new claims did not include new subject-matter.

The feature that the fixture supported the viewing device for movement within the optics bore along the longitudinal axis of the bore to extend or retract the viewing device relative to said distal working end of the cannula was not an essential feature because, as

the application as originally filed made clear, it was only necessary to make the viewing device movable during a surgical procedure for the device to be operable without a fluid-maintained working space.

Neither of the devices of E1 and E2 was suitable for use in percutaneous surgery without a fluid-maintained working space. The working channel of E2 was not open at the proximal end in the sense of the patent in that the surgeon could not insert instruments during surgery and manipulate them freely when the viewing device was mounted in place.

Starting from E1 as the closest prior art document, the patent defined the problem of operating the device without a fluid-maintained working space. The skilled person would not consult E2 because the device thereof could not operate without a gas.

Reasons for the decision

1. The appeal is admissible.

2. Article 100 (c) EPC 1973 - main request

2.1 The appellant has the following objections to claim 1:

(a) Original claim 8 relates to "A device for use in percutaneous spinal surgery", whereas granted claim 1 relates to "A device suitable for use in percutaneous surgery", and this makes the claim unjustifiably broader.

(b) Original claim 8 relates to a device for percutaneous spinal surgery whereas granted claim 1 relates to a device for use in percutaneous surgery. The omission of "spinal" is unjustified.

(c) Claim 1 should define a working channel between said ends having a second dimension substantially equal to said first inner dimension.

(d) Claim 1 should define a viewing element mounted inside said cannula adjacent said working channel.

(e) Original claim 8 defines a viewing device with a lens. There is no lens in present claim 1.

(f) The last feature of original claim 8: "said optics bore sized to removably receive said viewing device therethrough, and said fixture supporting said viewing device for movement within said optics bore along the longitudinal axis of said bore to extend or retract said lens relative to said distal working end of said cannula" has been omitted from granted claim 1.

2.2 The Board disagrees with the appellant on all the above counts. Claim 1 is an amended version of original claim 8 and the amendments are allowable for the following reasons:

(a) The expression "for use" is synonymous with "suitable for use". The sense of the claim is not altered by the use of the one expression or the other.

(b) The broadening of the claim is justified by the application as originally filed (WO 97/34536), see page 1 line 7 and page 49, lines 12-18, for example.

(c) Original claim 8 does not define this feature, it was in original claim 1.

(d) Original claim 8 does not define this feature also, it was in original claim 1.

(e) The lens is not clearly relevant to the invention, having regard to the problem and solution (see point 3 below). See also Summary of invention on page 6 of the application, which suggests that the use of a lens is optional.

(f) According to the description the feature that ensures that there is no need to provide a fluid workspace is that the optics are movable (page 15, lines 31-32), and conversely, prior art devices do need a fluid because the optics are fixed (page 31, lines 3 to 12). The optics need not be retractable/extendable and this is not an essential feature of the invention. This omission is justified, accordingly.

3. The technical problem and solution of the patent in suit

The patent in suit relates to a device for performing percutaneous surgery, including a cannula which defines a working channel sized to receive a tool therethrough,

and a viewing element mounted adjacent the working channel. The patent reviews the pertinent prior art, including document E1, which relates to percutaneous surgery devices which operate with a fluid-maintained working space, and sets out some disadvantages of a fluid-maintained working space (paragraph [0011] of the patent).

The solution proposed by the patent is set out in paragraph [0033], which says "Because the optics are movable, it is not necessary to provide a fluid-maintained work space. The optics can be removed, cleaned and replaced while the cannula is percutaneously positioned within the patient over the working space. Any configuration which allows the optics to be movably supported adjacent the working channel 25 is contemplated".

It is noted that this solution means that the optics are movable during a surgical procedure, as stated in claim 1 as granted ("during surgery"). As the respondent's representative explained at the oral proceedings, previously detritus was removed by a fluid, but if the optical system is movable, then it is sufficient to move it away from the detritus while continuing to observe the surgical site. Thus it is possible to perform a surgical procedure without a fluid-maintained working space.

4. Novelty - main request

4.1 The Board is of the view that neither of the devices of E1 and E2 is suitable for use in percutaneous surgery without a fluid-maintained working space. While it

would be sufficient for the devices to comprise optics which were movable during a surgical procedure for them to be suitable for use in surgery without a fluid-maintained working space, this is not the case as demonstrated below.

4.2 E1: the device of E1 is suitable for use in percutaneous surgery, but it cannot be used without a fluid-maintained working space. The only disclosure of two cannulae (30a and 30b) positioned adjacent each other by a fixture (60) is with respect to Figure 12 and the corresponding description. The fixture 60 is a sealing adapter mounted at the proximal ends of the cannulae 30a, 30b, and arthroscopic examination is performed through one cannula while a tool is passed through the other cannula. Direct visualisation is possible by passing a saline solution through one cannula and evacuating it through the other one.

Visualisation would not be possible without the saline solution. Thus, there is no disclosure of a viewing device disposed adjacent the distal end of the cannula in a non-fluid environment.

The appellant argued that E1 states that "A saline solution may be passed through via the arthroscope through one cannula", which means that the saline solution is optional. This argument is not correct since "may be" refers to how the saline solution is passed (e.g. via the arthroscope) and not to the optional use of the saline solution. That a saline solution is necessary for direct visualisation is confirmed by the word "thus" at line 6 of column 6 of E1.

4.3 E2: the rectoscope of E2 is not suitable for use in percutaneous surgery.

A rectoscope has a relatively large diameter since it is for passing through a natural body cavity and it must form a gas seal with it. By contrast a device for percutaneous surgery must be minimally invasive, and the person skilled in the art would not seriously contemplate using a rectoscope for percutaneous surgery. The diameter of the rectoscope of E2 is further augmented by the distal sealing cap 2, which would have to be removed if the device were to be inserted percutaneously. Thus, the device, without modification, is not clearly suitable for use in percutaneous surgery.

The device of E2 is also not suitable for use without a fluid-maintained working space. The tenor of the entire document is that the device must be operated in a gas-sealing manner. Thus, the tube 1 is sealed to the housing by a sealing ring 3a, the instrument carrier 4 is sealed to the housing 3 by a sealing ring 10 and may be turned without loss of gas, and the viewing element 12 and the instruments are sealed by a sheath 11 and sealing cap 22, respectively. The device is operated by supplying gas through passages 24 and 25 in order to expand the rectal cavity.

It would go against the entire teaching of E2 to use this device without a gas. Nevertheless, even if the device were to be used without a gas the gas passages would be removed for ease of use because they are bulky and would hinder the operation. The person skilled in the art would not contemplate use of this device

without gas without first modifying the device, accordingly.

4.4 The appellant also argued that by virtue of the fact that the viewing optics of E1 and E2 are movable the devices must also be suitable for use without a fluid-maintained working space. This is not correct. As indicated in point 3 above, the meaning of this part of claim 1 is that the viewing optics must be movable during surgery. The viewing optics of E1 and E2 are not movable during a surgical procedure.

In E1 the arthroscope is passed in sealing manner through one of the bores 62a or 62b of the sealing adaptor 60. If the arthroscope were to be moved the seal would be broken. This must be avoided since a saline solution is passed via the arthroscope, so that it would not be moved during use in surgery.

It is an object of the invention of E2 to be able to study tissue lying at different depths of the rectum (column 2, lines 15 to 19). To achieve this different lengths of disposable tubing are used and removably attached to the device (column 2, lines 20 to 25) by means of a lever 14 and an eccentric mechanism 15 (column 3, lines 33 to 38). This means that once a given tube is attached to the device, its position is fixed for the duration of an operation.

To summarise, the argument that the person skilled in the art would consider using the devices of E1 or E2 without a fluid runs contrary to the teaching of these documents and is an ex post facto argument.

4.5 A further difference between the claimed device and that of E2 is that in the device of E2 the fixture (3, 4) is not arranged such that when it is mounted to the cannula the working channel is open at the proximal end of the cannula.

By this, in claim 1 of the opposed patent, is meant that when the fixture is mounted to the cannula and the device is ready for use in a surgical procedure the working channel is open to the environment at its proximal end. This enables the surgeon to insert one or more instruments into the cannula and to manipulate them freely during the surgical procedure.

In E2 once the fixture 3, 4 is mounted to the cannula and the viewing element 12 inserted and the device made ready for use by attaching the extension 20, the working channel of the cannula 1 is not open to the environment at its proximal end.

4.6 For the above reasons neither of the devices of E1 or E2 anticipates the subject-matter of claim 1.

5. Inventive step - main request

5.1 The closest prior art is document E1 because it describes a percutaneous surgical device for accessing a herniated intervertebral disc. This document recognises the fact that the internal diameter of an access cannula limits the type and size of instruments that would allow for the simultaneously visualisation and surgical treatment (see the sentence linking columns 1 and 2). The problem is solved in E1 by using two cannulae, respectively for the optics and for a

tool. Therefore E1 is concerned with the same problem as that addressed in the patent under opposition.

E2 is not the correct starting point for the assessment of inventive step, merely on the basis of a similarity to the claimed device. The starting device for evaluating the inventive merit of an invention must be suitable for the desired use, which is for percutaneous surgery, and this is the device of E1.

5.2 Starting from E1 and bearing the technical problem in mind (see point 3 above) the skilled person would not be motivated to consider prior art relating to a rectoscope for use in a gas-filled environment. The skilled person would consider looking at suggestions in a neighbouring or broader technical field, but only be to the extent that they addressed the same problem. Since the present problem is specific to percutaneous surgery where minimal invasion is a prerequisite, and is also concerned with techniques that do not use fluid, the skilled person would have no reason to consider the disclosure of E2.

5.3 However, as shown above, even if E2 were to be considered it would not suggest operation in a fluid-free environment. In fact neither this document nor E1 discusses the present technical problem, which itself is indicative of an inventive step. Since these documents are silent as to the problem they also cannot suggest a solution thereto.

5.4 Therefore, the subject-matter of claim 1 involves an inventive step.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar The Chairman

D. Sauter M. Noel