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D E C I S I O N
of 17 January 2006

Case Number: T 0730/03 - 3.4.02

Application Number: 97907889.6

Publication Number: 0883793

IPC: G01B 11/12

Language of the proceedings: EN

Title of invention:
Method and apparatus for performing optical measurements using a fiber optic imaging guidewire, catheter or endoscope

Applicant:
MASSACHUSETTS INSTITUTE OF TECHNOLOGY

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 83, 123(2)

Keyword:
"Sufficiency"
"Added subject-matter"

Decisions cited:
T 0032/84

Catchword:
-

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Case Number: T 0730/03 - 3.4.02

D E C I S I O N
of the Technical Board of Appeal 3.4.02
of 17 January 2006

Appellant: MASSACHUSETTS INSTITUTE OF TECHNOLOGY
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Representative: Greenwood, John David
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 14 February 2003 refusing European application No. 97907889.6 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: A. Klein
Members: M. Rayner
M. Vogel

Summary of Facts and Submissions

I. The present appeal is against the decision of the examining division refusing European patent application number 97 907 889.6 (International Publication Number WO97/32182) concerning in situ imaging of a structure. The examining division decided that the subject matter of the independent claim of the main request before it had been amended in such a way as to introduce subject matter which extends beyond the original disclosure, contrary to Article 123(2) EPC.

In particular, one feature which the division considered could not be derived directly and unambiguously from the documents as filed reads "the optical system is mechanically coupled to the distal end of the rotatable fibre." The division considered the original disclosure does not provide detailed descriptions of the rotating fibre embodiments.

With respect to the invention as claimed, the feature of fixed or mechanical coupling of rotating fibre and optical system is essential, but is not disclosed in the combination claimed. Lacking such an essential feature, the claimed invention is therefore insufficiently disclosed for being successfully carried out and the requirements of Article 83 EPC are not met.

While the division considered features objectionable under Article 123(2) EPC were deleted in claim 1 of the first auxiliary request presented to it, corresponding arguments relating to sufficiency nevertheless applied. The division concluded that the first auxiliary request failed the requirements of Article 83 EPC. Similar

objections arose against the second auxiliary request presented to the examining division.

II. The appellant requests that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution on the basis of its main request or, in the alternative, on the basis of one of auxiliary requests 1 to 4.

In support of its position, the appellant referred to the headnote of decision T 32/84, which it understood as supporting its case on sufficiency as, even if the assessment of lack of disclosure were correct, the examining division should have gone on to consider if the teaching were nonetheless sufficient. The subject matter claimed is sufficiently disclosed and support is present in the documents as filed for a feature denoted as feature (g) in the request submitted with the statement setting out the grounds for appeal. Feature (g) is worded "a rotatable optical system coupled to said distal end of said optical fibre so as to be rotatable thereby". The appellant pointed to a disclosure in the documents as filed reciting that the rotational scanning mechanism causes rotation of the optical fibre or a component of an optical system disposed at the distal end of the optical fibre. Moreover synchronous laser firing in the embodiment of Figure 19 means the optical system is clearly rotatable by the fibre. The coupling between the fibre and optical system, say a GRIN lens, is not specifically described but the appellant contended it is entirely within the normal technical abilities of a person skilled in the art to provide the required coupling without inventive effort.

Since the appellant had had no opportunity to present arguments in support of patentability to the examining division, remittal was requested to allow consideration of patentability before two instances.

III. Consequent to an auxiliary request of the appellant, the board appointed oral proceedings. In a communication attached to the summons, the board commented that the optical fibre 44 is in a shaft 46 (sometimes called a torque cable). Thus, either both the fibre 44 and the shaft 46 are driven or the shaft 46 alone. In the case of Figure 19, the laser firing in synchronism with fibre rotation says nothing about any driving connection between the fibre and the optics. It can be seen that Figure 19 shows an arrangement not dissimilar from Figure 7C for the optics. This configuration is present in Figure 9, where the mirror 1158 is driven via torque cable 1146. The board doubted whether the arguments of the appellant mentioning not needing inventive effort or, that this was self evident to the skilled person, amounted to teaching that the fibre drives the optical system. If the feature denoted as (g) was significant, one might have expected it to have been given as much prominence as other disclosures.

IV. In reply to the communication of the board and in preparation for the oral proceedings the appellant filed four auxiliary requests and argued that in Figure 12 of the application and the corresponding description at page 16, the only components within the hollow bore 343 of the housing 342 are a rotating optical fibre 344, a lens 358 and an optical system 354 including a beam director 358. The housing includes a

cylindrical window 360. The beam is rotated to provide a circumferential scan of neighbouring tissue by rotation of the beam director (a planar surface) about the longitudinal axis of the probe. The fibre 344, lens 356 and beam director 358 are clearly mechanically coupled to each other otherwise the beam director 358 would not be maintained in position relative to the fibre/lens axis. This mechanical coupling also provides that the director rotates as the rotating fiber rotates. That is, feature (g) of claim 1 is clearly and unambiguously disclosed by the application as filed. Fabrication techniques for joining these components were very well established at the priority date of the application and so the coupling of the components is adequately supported by the description.

The independent claim 1 of the first auxiliary request is a combinations of originally filed claims, namely claims 1, 8 and 12. Auxiliary request 2 is directed to the specific embodiments illustrated by Figure 9 in particular and adopting the wording of page 14 lines 9 to 10.

V. During the oral proceedings, the appellant argued that due account should be taken of what the skilled person would take as read in respect of the connection between the optical fibre and optical system. There are four aspects to this:

1. The application as filed contains nothing incompatible with the fibre being fixed to the optical system.

2. The fibre and optical system do operate as a unit, even where the torque cable is not mentioned, so that fixing is implicit.

3. There is nothing in the rotating system showing where the shaft is fixed to the optical system so that other than fibre attachment, there is nothing disclosed.

4. Alignment is with a hair's breadth fibre to which attachment of an optical system was well known. Attempting to make the joint by sliding the fibre down a torque cable was not a realistic option.

The appellant referred to page 8 not reciting driven solely thereby and the reference to optical fibre as shown in Figure 10. Reference was also made to pages 11 and 13 indicating that the rotational scanning mechanism causes rotation of the fibre or a component of the optical system. Moreover in the sentence in line 4 on page 11, the word preferable is used, meaning that the optical fibre is not necessarily encased in a hollow flexible shaft. An optional hollow shaft means the optical fibre can drive the shaft. Therefore direct driving is described sufficiently.

VI. Claim 1 according to the requests of the appellant is worded as follows.

Main Request

"1. An apparatus for performing imaging of a structure (14) in situ comprising:
an optical radiation source (2);
an interferometer (4) coupled to said optical radiation

source; said interferometer comprising a reference optical reflector (12), a means for combining optical radiation (6) and a detector (16) arranged to generate a signal in response to optical radiation reflected from said reference reflector (12) and optical radiation reflected from said structure (14); and wherein said means for combining optical radiation (6) is arranged to receive and combine optical radiation from said reference reflector (12) and said structure (14) and to direct combined light to said detector (16); and a probe unit comprising:
an elongated housing (42) defining a bore and having a sidewall and two ends and an optical fibre means (44) for transmitting optical radiation from said optical radiation source to said structure to illuminate said structure (14), said optical fiber means (44) having a proximal end and a distal end positioned within and extending the length of said bore of said elongated housing (42); the apparatus being characterized by:
said optical fiber means(44) being a single, single-mode fiber (44);
the housing having a transparent window in the sidewall in the area of the distal end of the housing (42);
a coupler coupling said optical radiation source to said proximal end of said fiber;
a rotatable optical system (54) coupled to said distal end of said optical fiber so as to be rotatable thereby, and positioned to transmit said optical radiation from said fiber to a structure (14) and to transmit reflected optical radiation from said structure to said distal end of said optical fiber(44);
a beam director arranged to direct said transmitted optical radiation from said distal end of said optical fibre;

a processor (18) arranged to generate an image of said structure in response to said signal from said detector (16);
said fiber (44) being rotatable within said bore; and comprising a drive shaft assembly mechanically coupled to said proximal end of said fiber (44) and arranged to cause rotation thereof."

Auxiliary Request 1

"1. An apparatus for performing imaging of a structure (14) in situ comprising:
an optical radiation source (2);
an interferometer (4) coupled to said optical radiation source; said interferometer comprising a reference optical reflector (12), a means for combining optical radiation and a probe unit; said probe unit comprising:
an elongated housing (42) defining a bore: an optical fiber means including at least one optical fiber (44), said optical fiber (44) having a proximal end and a distal end positioned within and extending the length of said bore of said elongated housing (42);
a coupler coupling said optical radiation source to said proximal end of said fiber;
an optical system (54) coupled to said distal end of said optical fiber (44), and positioned to transmit said optical radiation from said fiber (44) to a structure (14) and to transmit reflected optical radiation from said structure (14) to said distal end of said optical fiber (44), wherein said probe unit comprises at least one rotating optical system (54) to direct optical radiation to said structure, and said fiber (44) is rotatable within said bore;
a drive shaft assembly mechanically coupled to said

proximal end of said fiber (44) causing rotation thereof,
a beam director (58) directing said transmitted optical radiation from said distal end of fiber (44);
a detector (16) arranged to generate a signal in response to optical radiation reflected from said reference reflector (12) and optical radiation reflected from said structure (14); and
a processor (18) arranged to generate an image of said structure (14) in response to said signal from said detector (16),
wherein said means for combining optical radiation, is arranged to receive and combine optical radiation from said reference reflector (12) and said structure (14) and to direct combined light to said detector (16)."

Auxiliary Request 2

"1. An apparatus for performing imaging of a structure (14) in situ comprising:
an optical radiation source (2);
an interferometer (4) coupled to said optical radiation source; said interferometer comprising a reference optical reflector (12), a means for combining optical radiation and a probe unit; said probe unit comprising: an elongated housing (1142) defining a bore; an optical fiber means including at least one optical fiber (1144), said optical fiber (1144) having a proximal end and a distal end positioned within and extending the length of said bore of said elongated housing (1142);
a coupler coupling said optical radiation source to said proximal end of said fiber (1144);
a rotating optical system coupled to said distal end of said optical fiber (1144), and positioned to transmit

said optical radiation from said fiber (1144) to a structure and to transmit reflected optical radiation from said structure (1114) to said distal end of said optical fiber (1144):
a beam director (1158) directing said transmitted optical radiation from said distal end of fiber (1144);
a detector (16) arranged to generate a signal in response to optical radiation reflected from said reference reflector (12) and optical radiation reflected from said structure (14); and
a processor (18) arranged to generate an image of said structure in response to said signal from said detector (16), wherein said means for combining optical radiation, is arranged to receive and combine optical radiation from said reference reflector (12) and said structure (14) and to direct combined light to said detector (16); and in which
the fiber is housed in a flexible torque cable (1146) which is coupled to the beam director (1158) and drivable in rotation by a motor (1174) to rotate the beam director (1158)."

The wording of auxiliary requests 3 and 4 is not given for the reason presented in section 8 below.

VII. At the end of the oral proceedings the board gave its decision.

Reasons for the Decision

1. The appeal is admissible.

2. *Teaching of the application*

2.1 The appellant did not dispute there not being an explicit disclosure of mechanical driving of the optical scan system by the optical fibre as unaided link in the drive chain. A number places in the application have been cited by the appellant as nevertheless giving the teaching. In detail, the relevant passages are as follows:-

2.2 A block diagram endoscope unit in Figures 1, 3 and 16 to 18.

2.3 In Figure 4, there is shown as first mentioned in the description in relation to Figure 6, an optical system 54 including a lens 56 and an optical beam director 58 (e.g. page 13, lines 21 to 22). The beam director 58 may include a lens, prism, or mirror constructed so as to minimize the effects of turbulence on the beam propagation. A rotational scanning mechanism (1)35 is shown, but exactly how it is connected to the optical system is indeterminate.

2.4 In Figures 7A to 7C, the angle of the emitted beam is changed to cause rotational scanning, extra optical components are shown in 7B and 7C, but the schematic nature of the drawings does not teach any details of their driving, indeed further details are said to be given in Figures 6 or 9 and 10, respectively.

2.5 The rotational scanning mechanism is said to be described in greater detail in Figure 8, but here it is not the distal end an what is said is that the optical connector 48 functions as the drive shaft, and in all embodiments the drive motor, via a gear mechanism, causes the rotatable fibre or a component of the optical system to rotate, i.e. there is no teaching that the optical fibre causes the optical system to rotate. Reference is again then made to Figure 6, where a lens 56 and beam director 58 are plainly shown as a unit with a diameter as large as the hollow flexible shaft 46, there is thus again no reason to suppose the optical fibre alone drives the optical system.

2.6 In Figure 9, the fibre is housed in a flexible torque cable 1146, which is connected to the drive gear mechanism. A mirror 1158 for beam directing is explicitly taught as connected to the torque cable, there is no question of it being driven by the optical fibre. A lens at the end of the fibre is also shown flush within the torque cable, implying it too is driven by the torque cable.

2.7 Figure 10 concerns a embodiment in which the fibre does not rotate. In Figure 11, fibre 44 is enclosed in a flexible torque cable 45 and the lens unit 56 is shown flush therewith. In Figure 12, the configuration of the rotating fibre is described as similar, i.e. the unreferenced component around the fibre 344 is a torque cable. The submission of the appellants that the only components shown are the fibre, lens and optical system including a beam detector is therefore not indicative of an absence of torque cable. The possibility of a stationary fibre is also mentioned. An attachment of

the shaft housing the rotating fibre to the inside of a metal guide wire is mentioned, but this gives no indication that the optical system is rotated by the fibre. The fibre and lens are therefore no more clearly mechanically coupled than the torque cable and lens. Therefore, contrary to the submissions of the appellant, the figure does not show that the fibre and not the torque cable rotate the optical system.

2.8 Figure 19 teaches that the firing of a laser is synchronised with rotational scanning of the optical fibre, but this is not a teaching that the optical fibre drives the optical system.

2.9 The board therefore failed to find a teaching of the optical system being rotated by the fibre in the application. In no case, for example, is the torque cable cut away in the vicinity of the optical system, it must therefore be concluded that at least part of the driving of the torque cable is always directly transmitted to the optical system. It can only be concluded that the "or" in the reference on pages 11 and 13 to the torque cable causing rotation of the fibre or optical system is an inclusive or.

3. *Interpretation applied by appellant*

3.1 In the statement of appeal the appellant contended that the application as filed clearly disclosed embodiments in which a single mode fibre is rotatable and which rotation causes a rotatable optical system that is coupled to the fibre also to rotate, thereby providing a scanning of the optical rotation. During the oral proceedings, it became apparent that the appellant

wished to have a patentable claim with features meaning, one way or another, a drive concept that an optical fibre is an unaided link in the mechanical drive chain of a rotating optical system, which system is positioned to transmit (reflected) optical radiation between the fibre and a structure to be examined. The case therefore turns on whether the teaching for this drive concept is sufficient and indeed if it was originally disclosed. For the reasons given in section 2 above, the board is of the view that a sufficient teaching along these lines is not present in the documents as filed. If, therefore, a claim is stretched by being construed as implicitly including features in this direction, the application is at least insufficient in the sense of Article 83 EPC so far as embodiments with such features are concerned. If such features are recited explicitly in the claim, and these features were not originally disclosed, then that claim contains explicit added subject matter and subject to objection under Article 123(2) EPC.

4. *Main Request - Sufficiency (Article 83 EPC)*

4.1 Claim 1 of the main request contains a feature worded "a rotatable optical system coupled to said distal end of said optical fibre so as to be rotatable thereby", which is the feature denoted as feature (g) by the appellant in the appeal proceedings. Since the claim includes the optical fibre being an unaided link in the mechanical drive chain of the optical system (in which the beam director can be included), the application is insufficient as the skilled person is not taught how such is to be carried out.

The four aspects advanced by the appellant in support of its case do not amount to convincing counter arguments because they refer in essence to what is not taught rather than positive teachings. In particular, none of the first three aspects (nothing incompatible, operation as a unit, no explicit fixing to shaft) apply any more to driving the optical system by the fibre alone than to driving the optical system by the fibre/torque cable. Whether or not the normal abilities of the skilled person include knowing how to attach optical components to fibres or shaft/torque cable is not the pertinent point, the point is that the rotation of the optical system by the fibre as unaided link in the drive chain is not taught. The fourth aspect (allegation that the only sensible joint is between the fibre and an optical component) cannot be taken as excluding an attachment of the shaft to the optical system, especially as for example the torque cable 1146 is stated to drive the mirror 1158 in Figure 9.

The reference to "preferably" in line 4 on page 11 in the sentence "The optical fibre 44 is preferably encased in a hollow flexible shaft 46" can apply to "encased" or to "flexible", and thus does not amount to a blanket statement that no shaft is necessary. Accordingly, it offers no sufficient teaching for the fibre alone driving the optical system.

4.2 The application does not therefore teach sufficiently how an optical fibre drives a system positioned to transmit (reflected) optical radiation between the fibre and a structure to be examined. Consequently, the main request fails to satisfy Article 83 EPC.

5. *Main Request - Amendments (Article 123(2) EPC)*

5.1 Since a teaching corresponding to feature (g) is not present in the application, its explicit recitation in claim 1 includes added subject matter.

5.2 According to the headnote of decision T 32/84, a person skilled in the art may put the invention into practice by applying a principle disclosed in the description which shows as essential to the invention an element shown not in the figure illustrating the invention as claimed but in another figure in the application provided that he does not make use of additional teachings and that no inventive step is involved. The present case is different because a teaching of driving by fibre alone is not present at all, which does not surprise the skilled person because use of a shaft or torque cable is taught. Therefore, the board does not see its approach in the present case as inconsistent with decision T 32/84.

5.3 Consequently, the claim 1 of the main request fails to satisfy Article 123(2) EPC.

6. *Auxiliary Request 1 - Sufficiency (Article 83 EPC)*

6.1 Claim 1 of auxiliary request 1 is derived from original claims 1, 8 and 9 with a number of minor improvements to the language used. The feature denoted as (g) is no longer present.

6.2 Nevertheless, it can be seen that rotation is mentioned in the following features of the claim "wherein said probe unit comprises at least one rotating optical

system (54) to direct optical radiation to said structure, and said fiber (44) is rotatable within said bore; a drive shaft assembly mechanically coupled to said proximal end of said fiber (44) causing rotation thereof,". In other words, the claim specifies that the drive shaft rotates the fibre and that the optical system rotates. The claim is silent about exactly what causes rotation of the optical system. The appellant has now brought the focus of the case onto this lack of teaching by stretching the construction of the claim to include, relying on the recitation in the claim of an optical system coupled to the distal end of said optical fibre as meaning not just optically but also mechanically coupled, the optical fibre being an unaided link in the mechanical drive chain of the optical system. However, as explained above, the teaching of the application is really that a torque cable is used, at least partly, in rotation of the optical system.

6.3 Therefore, embodiments now envisaged in claim 1 of auxiliary request 1, like those in claim 1 of the main request, derive form a teaching which is not sufficient, i.e. it's the subject matter of claim 1 does not satisfy the requirements of Article 83 EPC because the skilled person is not sufficiently taught to carry out the invention for embodiments where the optical fibre, as unaided link in the drive chain, drives the optical system.

7. *Auxiliary Request 2 - Amendments*

7.1 In this request the mechanical drive chain involved in an optical system directing transmitted optical radiation from the distal end of the fibre is specified, i.e. a flexible torque cable coupled to the beam director and drivable by a motor to rotate the beam director. Therefore, a system positioned to transmit (reflected) optical radiation between the fibre and a structure to be examined is sufficiently taught. Moreover, original disclosure for the amended claim is provided by, for example, Figure 11 and the associated description. The board therefore considers Articles 123(2) and 83 EPC to be satisfied by this claim.

7.2 The reasons for refusal given in the decision under appeal are not pertinent to claim 1 of auxiliary request 2. The board has not examined the application in any other respect. In order now to give the appellant the opportunity to present its case before two instances and consequent to the corresponding request of the appellant, the board considers it appropriate to remit the case to the first instance for completion of the examination.

8. *Auxiliary Requests 3 and 4*

8.1 Since auxiliary request 2 is not in contravention of Article 123(2) or 83 EPC, consideration of auxiliary requests 3 and 4 in this respect is not necessary in the present decision.

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 for further prosecution on the basis of claim 1 of auxiliary request 2, filed during the oral proceedings of 17 January 2006.

The Registrar: The Chairman:

M. Kiehl A. G. Klein