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D E C I S I O N
of 27 July 2005

Case Number: T 0365/03 - 3.2.2

Application Number: 93112269.1

Publication Number: 0590268

IPC: -

Language of the proceedings: EN

Title of invention:

Fiber Optic Probe System for Spectrally Diagnosing Tissue

Patentee:

Massachusetts Institute of Technology

Opponent:

Keiko Okumura

Headword:

-

Relevant legal provisions:

EPC Art. 52(1), 56

Keyword:

"Inventive step (yes, auxiliary request)"

Decisions cited:

-

Catchword:

-



Case Number: T 0365/03 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 27 July 2005

Appellant:
(Opponent)

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Respondent:
(Proprietor of the patent)

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Representative:

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Decision under appeal:

Interlocutory decision of the Opposition
Division of the European Patent Office posted
15 January 2003 concerning maintenance of
European patent No. 0590268 in amended form.

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
U. Tronser

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. 0 590 268. The decision was dispatched on 15 January 2003.

The appeal and the fee for the appeal were received on 25 March 2003. The statement setting out the grounds of appeal was received on 23 May 2003.

The opposition was filed against the whole patent and based on Article 100(a) EPC (lack of novelty and inventive step).

The opposition division held that claims 1 and 2 of the main request then on file did not involve an inventive step, and claims 1 and 2 of the first auxiliary request were objectionable under Articles 123(2) and (3) EPC. The second auxiliary request was found to meet the requirements of the EPC.

- II. The following documents are of interest for the present decision:

A: JP-A-56-95064 and its English translation
B: JP-A-54-125886 and its English translation
C: JP-A-59-139237 and its English translation
H: JP-A-55-59404 and its English translation.

III. Oral proceedings were held on 27 July 2005.

Appellant requested that the decision under appeal be set aside and that European patent no. 0 590 268 be revoked.

Respondent (patent proprietor) requested that the appeal be dismissed and that the patent be maintained on the basis of claims 1 to 24 of the main request submitted at the oral proceedings, or claims 1 to 23 and description columns 5 and 6 submitted at the oral proceedings, description columns 1 to 4 and 7 to 32 and Figures 1 to 28B as granted (auxiliary request).

IV. The independent claims 1, 2, and 16 of the main request read as follows:

"1. A system for diagnosing material within a lumen of a patient comprising: a diagnostic probe; a conventional, non-laser light source (98) that is optically coupled to the probe to irradiate tissue with light; a spectral analyzer (60, 65) for separating selected wavelengths light from the light that returns from the tissue through the probe to the analyzer (60, 65); the probe comprising a catheter (10) having a plurality of optical fibers (20a, 20b, 20b') including a central fiber (20a) and a concentric spaced apart array of optical fibers (20b, 20b') at a distal end of the probe such that said plurality of fibers (20a, 20b, 20b') are secured to each other in said spaced apart array within a plug (11) at said distal end of the catheter (10), at least one of the fibers being coupled to the conventional, non-laser light source; a solid state diode array detector (70) coupled to at least one

of the optical fibers extending through the probe that receives separated wavelengths of fluorescent light returning from the tissue without a fluorescence enhancing agent; and a computer (80) for processing signals from the detector (70) generated in response to the detected separated light and a memory for storing data, the memory having reference data to compare with the detector signals."

"2. A system for diagnosing material within a lumen of a patient comprising: a diagnostic probe; a laser light source (98) that is optically coupled to the probe to irradiate tissue with light; a spectral analyzer (60, 65) for separating selected wavelengths light from the light that returns from the tissue through the probe to the analyzer (60, 65); the probe comprising a catheter (10) having a plurality of optical fibers (20a, 20b, 20b') including a central fiber (20a) and a concentric spaced apart array of optical fibers (20b, 20b') at a distal end of the probe such that said plurality of fibers (20a, 20b, 20b') are secured to each other in said spaced apart array within a plug (11) at said distal end of the catheter (10), at least one of the fibers being coupled to the laser light source; a solid state diode array detector (70) coupled to at least one of the optical fibers extending through the probe that receives separated wavelengths of Raman scattered light returning from the tissue; and a computer (80) for processing signals from the detector (70) generated in response to the detected separated light and a memory for storing data, the memory having reference data to compare with the detector signals."

"16. Use of a fiber-optic system according to one of the preceding claims for diagnosing tissue after removal from a patient comprising: positioning a distal surface of a probe adjacent to tissue to be diagnosed; illuminating the tissue with a selected wavelength of light that is transmitted through the probe, the probe comprising a catheter having a plurality of optical fibers including a central fiber and a concentric spaced apart array of optical fibers at a distal end of the probe such that said plurality of fibers (20a, 20b, 20b') are secured to each other in said spaced apart array within a plug (11) at said distal end of the catheter (10) thereby inducing fluorescent or Raman scattering of light from the tissue without the use of a fluorescence enhancing agent; collecting the fluorescent or Raman scattered light with the optical fibers (20) extending through the probe (10) and separating the collected light into a plurality of wavelengths; detecting the fluorescent or Raman scattered light with a solid state diode array detector (70); and analyzing the fluorescent or Raman scattered light returned from the tissue by comparing the detected light with a reference to diagnose the tissue."

The independent claims 1, 2, and 15 of the auxiliary request read as follows:

"1. A system for diagnosing material within a lumen of a patient comprising: a diagnostic probe, the probe comprising a catheter (10) having a plurality of optical fibers (20a, 20b, 20b'); a conventional, non-laser light source (98) that is optically coupled to the probe to irradiate tissue with light; an optical

fiber selector (74) to selectively control delivery of light into one or more of a plurality of optical fibers in the probe; a spectral analyzer (60, 65) for separating selected wavelengths light from the light that returns from the tissue through the probe to the analyzer (60, 65); at least one of the fibers being coupled to the conventional, non-laser light source via the optical fiber selector (74); a solid state diode array detector (70) coupled to at least one of the optical fibers extending through the probe that receives separated wavelengths of fluorescent light returning from the tissue without a fluorescence enhancing agent; and a computer (80) for processing signals from the detector (70) generated in response to the detected separated light and a memory for storing data, the memory having reference data to compare with the detector signals."

"2. A system for diagnosing material within a lumen of a patient comprising: a diagnostic probe, the probe comprising a catheter (10) having a plurality of optical fibers (20a, 20b, 20b'); a laser light source (98) that is optically coupled to the probe to irradiate tissue with light; an optical fiber selector (74) to selectively control delivery of light into one or more of a plurality of optical fibers in the probe; a spectral analyzer (60, 65) for separating selected wavelengths light from the light that returns from the tissue through the probe to the analyzer (60, 65); at least one of the fibers being coupled to the laser light source via the optical fiber selector (74); a solid state diode array detector (70) coupled to at least one of the optical fibers extending through the probe that receives separated wavelengths of Raman

scattered light returning from the tissue; and a computer (80) for processing signals from the detector (70) generated in response to the detected separated light and a memory for storing data, the memory having reference data to compare with the detector signals."

"15. Use of a fiber-optic system according to one of the preceding claims for diagnosing tissue after removal from a patient comprising: positioning a distal surface of a probe adjacent to tissue to be diagnosed; the probe comprising a catheter (10) having a plurality of optical fibers illuminating the tissue with a selected wavelength of light that is transmitted through an optical fiber selector (74) selectively controlling delivery of light into one or more of a plurality of optical fibers in the probe and through the probe, thereby inducing fluorescent or Raman scattering of light from the tissue without the use of a fluorescence enhancing agent; collecting the fluorescent or Raman scattered light with the optical fibers (20) extending through the probe (10) and separating the collected light into a plurality of wavelengths; detecting the fluorescent or Raman scattered light with a solid state diode array detector (70); and analyzing the fluorescent or Raman scattered light returned from the tissue by comparing the detected light with a reference to diagnose the tissue."

V. The Parties argued as follows:

(a) Appellant

The only essential difference between the system of claim 1 of the main request and that of document B was that the claim defined a spaced apart array of fibers, and the technical problem this solved was to form slightly overlapping light beams. The solution to this was given by document H which disclosed a concentric array of fibers spaced apart from a central fiber. The fibers of this document were separated by a relatively thick cladding, and the ends of the fibers were solidified by an adhesive and cut and ground, and for this to be possible there must be a plug at the end of the fibers. In view of documents B and H, therefore, claim 1 did not involve an inventive step.

As regards claim 1 of the auxiliary request, the patent itself admitted that selectors were known in the prior art. It was unclear what problem this feature of claim 1 solved and, moreover, document C suggested a selector as defined in claim 1 of the auxiliary request so that this feature was also not inventive.

(b) Respondent

In the patent in suit the catheter went right up to the tissue, as shown in Figure 4, and the light spots overlapped at the tissue close to the ends of the fibers. By contrast the light spots in the system of document H would not overlap close to the ends of the fibers. The apparatus of Figure 4 was suitable for both treatment and diagnosis so that even though Figure 4

related to treatment the overlapping feature was also relevant for diagnosis.

The prior art, including document H, did not disclose a spaced apart array of fibers in a catheter, or a plug at the end of the fiber array. It was not, therefore, possible to combine documents B and H.

As for claim 1 of the auxiliary request, this involved an inventive step since the claimed device enabled selected fibers to be illuminated, which improved the resolution with which diagnosis could be performed. The prior art only disclosed illuminating the entire array of fibers which did not permit such resolution and, therefore, did not suggest the claimed device.

Reasons for the decision

1. *Admissibility*

The appeal was filed on 25 March 2003 in the name of Keiko Negishi, who had changed her name to Keiko Okumura, (which was reported to the authorities on 15 December 2003). During the oral proceedings before the Board the respondent stated that it no longer challenged the fact that Keiko Okumura was entitled to appeal the decision of the opposition division. Since the appellant has proved that she is one of the two daughters of Yaeko Okumura, and that her sister chose not to take part in the appeal proceedings, the Board has no doubt that Keiko Okumura has succeeded to the right of the opponent to appeal.

The appeal complies with Articles 106 to 108 and Rule 64 EPC and is admissible.

2. *Amendments*

The appellant had initially raised objections to the claims of the main request under Article 84 EPC and Article 123(2) EPC, but withdrew these at the oral proceedings.

Claims 1 and 2 of the auxiliary request were formed, like claims 1 and 2 of the main request, by splitting claim 1 as granted into one claim including a laser light source and another claim including a non-laser light source. Otherwise, these claims consist essentially of a combination of claims 1 and 5 of the claims as granted and meet the requirements of Article 123(2) and (3) and are allowable. Claim 15 is similarly allowable.

3. *Novelty*

Novelty of the subject-matter of the claims of either request was not disputed by the respondent, and the Board concurs with this opinion.

4. *Inventive step (Claim 1 of the main request)*

- 4.1 Document B is the closest prior art for claim 1. This document discloses a system for diagnosing material within a lumen of a patient, comprising a diagnostic probe (2, 3), a conventional, non-laser light source (9) that is optically coupled to the probe to irradiate tissue with light, a spectral analyzer (10 to 13) for

separating selected wavelengths of light from the light that returns from the tissue through the probe to the analyzer, the probe having a plurality of optical fibers (2, 3) including a central fiber and a concentric array of optical fibers (claim 2) at a distal end of the probe such that said plurality of fibers are secured to each other in said array within a plug (18, see page 12, lines 4 to 6 of the English translation) at said distal end of the catheter, at least one of the fibers being coupled to the conventional, non-laser light source, a solid state array detector (14) coupled to at least one of the optical fibers extending through the probe that receives separated wavelengths of light returning from the tissue without a fluorescence enhancing agent, and a computer (Figure 6a) for processing signals from the detector generated in response to the detected separated light.

Document B describes (the last part of page 11) an end stopper which fixes the end parts of the optical fibers. The Board considers this feature to be a plug since it performs the same function as the plug of the patent in suit and, moreover, the expression "plug" is very general and covers the stopper of document B.

4.2 The system of claim 1 differs from this system by virtue of the following features:

- (a) The system examines fluorescent light returned from the patient.
- (b) The probe comprises a catheter.
- (c) The fiber array is spaced apart at a distal end of the probe.

- (d) The detector array is a diode array.
- (e) The computer has a memory for storing reference data to compare with the detector signals.

4.3 The differences (a) to (e) are technically unrelated to each other, so they may be inspected individually for inventive step.

The Board considers each of the features (a), (b), (d) and (e) to be trivial in the context since measuring body parameters using a catheter is commonplace nowadays, as is the use of diode array detectors and the use of a computer to store reference data and to automate measurements. Moreover, the person skilled in the art knows that spectral light from body tissue has a characteristic spectrum, regardless of whether the emission spectrum, the absorption spectrum, the fluorescent spectrum, etc is examined, all these methods being equivalent in the context, and fluorescence spectroscopy is one known diagnostic method (see paragraph (2) on page 6 of document A, for example).

The respondent appears to agree with this analysis since it has not argued that the inclusion of any of these features involves an inventive step.

4.4 The respondent has, on the other hand, argued that the spaced apart array of fibers provides some technical advantages which justify patentability of the claimed system. The argument is to the effect that the spaced apart array enables the adjacent spots of emitted light to overlap, as described in column 12, lines 10 to 19, and the spacing is designed in conjunction with other

optical components to provide efficient coupling of the backscattered light into the distal ends of the fibers.

- 4.5 These arguments, regarding the technical effect of a spaced apart array of fibers at the distal end of the probe, are not convincing for the following reasons:

The patent does not clearly disclose the technical effect of spacing the fibers apart. The passage in column 12 to which the respondent refers in this respect discusses the advantages of the embodiment of Figure 4, and says "In the embodiment of Fig. 4 the optical fibers 20a-c' are arrayed such that each of the laser spots 27a-c' on the exterior surface of the optical shield 12 formed by exiting laser beams 29a-c' slightly overlap with adjacent spots". However, it is not stated which feature causes the overlapping of adjacent spots, this could be caused by a number of factors, for example, the fiber ends being splayed apart, the fiber ends being spaced apart, the degree of beam divergence, the distance between the fiber ends and the optical shield 12, etc. Therefore, this passage does not clearly disclose any technical effect of the fibers being spaced apart from each other.

- 4.6 Moreover, this passage says that the overlapping of the spots "insures that any and all plaque 34 in contact with the distal end of the optical shield 12 can be irradiated and removed by selecting the correct optical fiber(s) 20a-c'. The overlap of spots 27a-c insures that laser radiation can be delivered through all of the surface of the distal end of the optical shield 12." Thus, the overlap is related to the use of the probe in the treatment mode. It is not clear what it

has to do with a diagnostic probe, which is what the claimed system relates to.

- 4.7 In the absence of a clear technical effect provided by the feature that the ends of the fibers are spaced apart, it cannot contribute an inventive step (see the Case Law of the Boards of Appeal of the EPO, 4th edition, English version, I.D.6.5).

Therefore, claim 1 of the main request does not involve an inventive step and the main request is not allowable.

5. *Inventive step (auxiliary request)*

- 5.1 Claims 1, 2, and 15 of the auxiliary request all comprise the feature according to which an optical fiber selector to selectively control delivery of light into one or more of a plurality of optical fibers in the probe is provided.
- 5.2 The selector is described in column 29 and serves to direct light from the source selectively to one or more fibers which, in turn, causes one or more of the distal ends of the fibers to illuminate and optically excite tissue to fluoresce. This arrangement may be used to scan the tissue by illuminating the fibers successively, in order to build up a spatially resolved diagnosis of the tissue.
- 5.3 The technical problem may, accordingly, be seen in improving the spatial resolution of a catheter diagnostic system.

- 5.4 This technical problem is not discussed in any of the documents A, B, C, or H. Nor is the use of a selector arrangement as claimed disclosed or suggested in any of these documents. In particular, Document C, which was the only document cited by the appellant against the auxiliary request, merely discloses that a filter may be interposed in the light beam, it does not disclose the use of a selector for selectively illuminating one or more optical fibers.
- 5.5 By virtue of the selector arrangement, the subject-matter of each of claims 1, 2, and 15 solves a particular technical problem by employing a combination of constructional features not known in the context. Therefore, independent claims 1, 2 and 15 involve an inventive step.
6. Therefore, the auxiliary request is allowable.

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 on the basis of claims 1 to 23 (auxiliary request) and description columns 5 and 6 submitted at the oral proceedings, description columns 1 to 4 and 7 to 32 and Figures 1 to 28B as granted.

The Registrar:

The Chairman:

V. Commare

T. K. H. Kriner