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D E C I S I O N
of 11 February 2005

Case Number: T 0171/03 - 3.2.2

Application Number: 90905231.8

Publication Number: 0465524

IPC: A61B 5/026

Language of the proceedings: EN

Title of invention:
Blood flow determination

Patentee:
BTG INTERNATIONAL LIMITED

Opponent:
Lisca AB

Headword:
-

Relevant legal provisions:
EPC Art. 56, 83
EPC R. 67

Keyword:
"Inventive step (main request, yes), sufficiency (yes),
procedural violation (no)"

Decisions cited:
-

Catchword:
-



Case Number: T 0171/03 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 11 February 2005

Appellant: BTG INTERNATIONAL LIMITED
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Respondent: Lisca AB
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Representative: Hytting, Kerstin Cecilia
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
26 November 2002 concerning maintenance of
European patent No. 0465524 in amended form.

Composition of the Board:

Chairman: T. K. H. Kriner
Members: S. S. Chowdhury
E. J. Dufrasne

Summary of Facts and Submissions

I. The appellant (patent proprietor, BTG International Ltd.) lodged an appeal against the interlocutory decision of the opposition division relating to European patent No. 0 465 524. The decision was dispatched on 26 November 2002.

The appeal and the fee for the appeal were received on 24 January 2003. The statement setting out the grounds of appeal was received on 4 April 2003.

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

The opposition division decided that the subject-matter of claims 1 and 13 of the main request did not involve an inventive step, but that the claims of the auxiliary request submitted at oral proceedings before the opposition division met the requirements of the EPC.

II. The Board has considered the following documents:

A1: US-A-4 579 430

A2: US-A-4 476 875

A4: EP-A-0 282 210

III. Appellant requests that the patent be maintained as granted (main request) or on the basis of claims according to the first to sixth auxiliary requests filed with the grounds of appeal. Oral proceedings are

requested if the main request is not granted.
Reimbursement of the appeal fee is requested because of a substantial procedural violation.

Respondent (opponent Lisca AB) has not made a submission in the appeal procedure.

IV. The independent claims 1 and 13 of the main request read as follows:

"1. A method of determination of blood flow using Doppler scattering of coherent laser light including: Scanning a beam (B) of laser generated light over a surface (T) beneath which blood flow in a vessel or vascular bed is to be determined, collecting (SM, RD) returning light scattered from the beam by the surface and by blood flowing beneath, measuring (RD) by detecting a spectrum of frequencies in said collected light, characterised in that a plurality of spectra of frequencies is detected by means of a plurality of detectors (RD) at a corresponding plurality of different points in space and blood flow in a vessel or vascular bed beneath said surface is determined (DA, F, IP) from differences in said corresponding ones of said plurality of spectra frequencies by eliminating spatially correlated signals from said collected light in order to provide a signal from which blood flow may be determined.

13. Apparatus to determine blood flow using Doppler scattering of coherent laser light including: a laser (L) for generating a beam (B) of laser light, means to scan (SM) said beam over a surface (T) beneath which blood flow in a vessel or vascular bed is to be

determined, means to collect (SM, RD) returning light scattered from the beam by the surface and by blood flowing beneath, means to detect (RD) a spectrum of frequencies in said collected light, characterised in that a plurality of detectors (RD) for detecting the spectra of frequencies at a corresponding plurality of points in space and means (DA, F, IP) to determine information relating to blood flow in a vessel or vascular bed beneath said surface from differences in said corresponding ones of said plurality of spectra of frequencies by eliminating spatially correlated signals from said collected light in order to provide a signal from which blood flow may be determined."

Claims 2 to 12 and 14 to 21 are dependent claims.

V. The Appellant argued as follows:

The impugned decision wrongly stated that the only difference between the method of claim 1 and the prior art method of A2 lay in the step of scanning the beam over a surface, there were further significant differences which the opposition division did not consider and hence it formulated the wrong technical problem. Moreover, it stated that a combination of A2 and A4 would yield the solution to the problem, which was also not correct since these documents could not be combined.

At the oral proceedings the opposition division rejected auxiliary requests I, III, IV, and V as being inadmissible for not being *prima facie* relevant under Articles 56, 84, and 123 (2) EPC. This restricted the rights of the patent proprietor since it was then left

with little freedom to amend the patent to overcome objections during the oral proceedings, which was the main purpose of such proceedings. Moreover, the opposition division had neither given sufficient reasoning of preliminary opinion in support of lack of inventive step nor granted the proprietor any leeway regarding filing auxiliary requests, which contravened the principle of good faith. Furthermore, the opposition division placed a higher importance on the interests of the opponent, who did not attend the oral proceedings, than on that of the patent proprietor, and did not provide adequate reasons for not admitting the amended claims. For these reasons a reimbursement of the appeal fee was justified.

The respondent has made no submissions during the appeal procedure.

Reasons for the Decision

1. The appeal is admissible.

2. *Novelty*

Lack of novelty is not a ground of opposition and was not considered by the opposition division of its own motion.

3. *Inventive step*

3.1 The patent provides a technique for the determination of blood flow by which a map of blood flow over a given area can be produced without contact with or invasion

of a subject. A laser beam of wavelength λ is scanned over the subject by a scanning mirror and the scattered light is directed to a receiving device having a plurality of photodetectors.

The scattered light consists of the wavelength λ of the initial beam, and additionally $\lambda \pm \delta\lambda$, where $\delta\lambda$ is the Doppler shifted wavelength caused by blood flow, which flow is made up of uncoordinated blood particles so that, because the blood particles have a random motion, the scattered light will be spatially uncorrelated. Additionally, the scattered light consists of the wavelength $\lambda \pm \Delta\lambda$, where $\Delta\lambda$ is the shifted wavelength caused by movement of the subject (owing to breathing for example). Over the small area of the beam the movement is the same so that this signal over the whole area will be spatially correlated, which means that this signal, representing movement artefacts, can be cancelled out.

Circuits for processing the signal from the receiving device include two analogue amplifiers, followed by a differential amplifier for eliminating the $\Delta\lambda$ component and then a filter. This filter has a response by which the output is proportional to frequency so as to extract the scatter-related information, represented by the $\delta\lambda$ component, resulting from blood flow motion. As the beam is scanned over the subject a picture of the blood flow may be formed in a monitor.

The stated object of the invention (column 1, lines 37 to 43) is to provide a technique by which a map of blood flow over a given area can be produced without contact or other invasive approach to a subject of an

examination. The solution is given by the scanning method defined in claim 1 and the scanning apparatus of claim 13.

3.2 The prior art

3.2.1 The Board considers document A1 to describe the closest prior art since it discloses a technique for the determination of blood flow without contact with or invasion of a subject, using a laser beam focussed on a subject, and directing the scattered light to a receiving device for measuring the Doppler shift. The impugned decision started from A2 as the closest prior art, but although this also relies on the Doppler shift principle, it does not describe a laser beam focussed on a subject, instead it employs a laser fibre in contact with the subject.

3.2.2 A1 describes a laser system as shown in Figure 1 for forming a high resolution image of the ocular fundus (eye retina) which has a rotating polygonal mirror and optical system which scans the laser beam across the fundus, and the reflected light is focussed onto a receiver whose signal is processed to form an image of the fundus on a TV monitor, the image being as shown in Figure 2. No blood flow information is provided by the apparatus of Figure 1, however.

Spatial blood flow information is provided by the apparatus shown in Figure 6. The laser beam is divided into two parts which are focussed on the retina by a lens, which is the lens of the eye (see column 9, lines 46 and 47). This means that the scanning system of Figure 1 is not used (despite claim 12 being

dependent on claim 7). The light scattered by the retina is detected and the speed of blood flow is determined. The principle used to detect flow velocity is by using a fast Fourier transform (ie exploiting the Doppler effect, see column 4, lines 41 to 43) but there is no cancellation to allow for body movement.

Moreover, the Figure 6 system is meant to be inserted at point (41) in Figure 1 (see column 9, lines 43 to 47). Since the Figure 6 system directs the light directly into the eye, this means that the scanning system of Figure 1 is by-passed. Instead of scanning the spatial blood flow distribution is apparently obtained by forming an interference pattern (see column 9, lines 26 to 33).

3.2.3 A2 describes a system in which laser light is applied to the skin via a fibre (Figures 3 and 7) and the light scattered by blood is collected by two adjacent fibres and fed to respective detectors. The difference signal at the output of an amplifier is a measure of the blood flow.

The object of this invention is to suppress high amplitude perturbations caused by mode interference and wide-band beam amplitude noise (see column 1, lines 45 to 52). In column 2, lines 13 to 23 it is stated that additionally wide-band noise as well as disturbances caused by intensity variations in the laser beam and by external optical disturbances will be suppressed, and also disturbances due to motion artefacts.

It is not clear what the motion artefacts referred to here are. Since the laser fibre is held against the

skin as stated at the end of column 4 and shown in Figure 7, this cannot refer to relative motion of the skin and the fibres. It is also noted that column 4, lines 12 to 22 mentions the various disturbances again but not motion artefacts.

The principle of this apparatus is the same as the principle used in the opposed patent in that both exploit the Doppler shift of frequencies caused by the random motion of blood cells, and disturbances caused by mode interference etc, which are in phase with each other, are cancelled out. There is, however, no clear teaching in A2 that movement artefacts owing to movement of the body may be cancelled out. Moreover, scanning to map the blood flow in a surface is not feasible in this system.

- 3.2.4 A4 describes apparatus for monitoring blood flow and includes a laser whose beam is converted into a line beam which is focussed onto the subject, and the scattered light falls as a speckle pattern on a linear sensor comprising many (256) detector elements which measure the signal intensity. Figure 2a shows the signal variation along the linear sensor array at two different times (respectively the full curve and the broken curve), the variation being large since the blood flow is at a high speed. In Figure 2b the same is shown for blood flow at a low speed, the temporal variation being correspondingly less. The variations for a given detector element are summed over time to give a measure of the blood flow speed. From the same circuit a map of blood flow may be constructed, giving the spatial variation of blood flow, using a scanning system as shown in Figure 5.

No spectral analysis is performed here, the evaluation is performed entirely in the time domain, so that the principle is different to that of the application where the evaluation is performed in the frequency domain. There is also no cancellation to allow for body movement.

- 3.3 The three documents, A1, A2, and A4 each relies on a different principle for measuring blood flow, so it is not clear that they may be combined with each other. Neither of the documents A1 and A4 suggests allowing the scattered laser light to illuminate a plurality of detectors in order to detect spatially correlated signals arising from body motion, and using a subtraction method for eliminating this source.

Although A2 does describe a subtraction method for eliminating correlated signals owing to mode interference and wide-band beam amplitude noise, and there is also mention of movement artefacts, it is not clear what these are, and it is not clear that these are due to movements of the body. The system of A2 is also not suitable for scanning which is necessary for creating a two-dimensional display.

- 3.4 Starting from the apparatus of Figure 6 of document A1 the patentee realised that movement artefacts could be reduced by using a subtraction method. Moreover, by scanning the laser beam over the subject a map of the blood flow in the surface could be obtained. These modifications are not suggested by the prior art documents A2 and A4, for which reasons the subject-matter of claims 1 and 13 involves an inventive step.

4. *Article 100(b) EPC*

Only claims 7 and 18 were attacked by the opponent who argued that no information was given as to how to cancel out the effect of body motions in order to achieve the object of the invention. It is clear from the patent specification, however, that correlated (in-phase) signals are eliminated by subtraction in the circuit described by reference to Figure 3. The principle is the same as in A2 for subtracting correlated signals, and body motion is a further source of such signals and they would be similarly eliminated. Therefore, no objection arises under Article 100(b) EPC.

5. *Procedural violation*

The appellant requests reimbursement of the appeal fee (Rule 67 EPC) since the opposition division did not allow auxiliary requests 1, and III to V. However, it appears from the minutes of the oral proceedings (point 5.3) and also from the decision (Facts and Submissions, point 9) that these requests were withdrawn. Moreover, the opposition division was, in any case, merely exercising its discretion under Article 114(2) EPC, and its decision not to allow *prima facie* unallowable requests at a late stage of the procedure was not unreasonable, and in the Board's opinion no procedural violation has occurred.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is maintained as granted.

The Registrar:

The Chairman:

V. Commare

T. K. H. Kriner