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DECISION of 25 September 2002

T 1088/00 - 3.2.3 Case Number:

Application Number: 96910119.5

Int. Publication Number: WO 96/33819

B08B 9/02, B08B 3/12, A61B 19/00 IPC:

Language of the proceedings: EN

Title of invention:

Method for cleaning a hollow medical instrument

Applicant:

Dawson, Lawrence Ralph

Opponent:

Headword:

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step - additional effect"

Decisions cited:

Catchword:



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Boards of Appeal

Chambres de recours

Case Number: T 1088/00 - 3.2.3

DECISION
of the Technical Board of Appeal 3.2.3
of 25 September 2002

Appellant: Dawson, Lawrence Ralph

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Representative: Davies, Christopher Robert

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Decision under appeal: Decision of the Examining Division 2.3.09.113 of

the European Patent Office dated 28 March 2000, posted on 6 April 2000, refusing European patent

application No. 96 910 119.5 pursuant to

Article 97(1) EPC.

Composition of the Board:

Chairman: C. T. Wilson Members: F. Brösamle

J. P. Seitz

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Summary of Facts and Submissions

In the oral proceedings of 28 March 2000 the examining division refused European patent application No. 96 910 119.5; the written decision was posted on 6 April 2000. The decision was based essentially on

(D1) JP-A-6-343607

and its English translation. The examining division argued that the claimed subject-matter was novel but not inventive.

- II. Against the above decision of the examining division the applicant appellant in the following lodged an appeal on 6 June 2000 paying the fee on the same day and filing the statement of grounds of appeal on 15 August 2000 in which he defended the claims underlying the impugned decision and restricted the claims on the basis of an auxiliary request to a piston pump to achieve a pulsed flow of cleaning fluid.
- III. Following the board's Communication pursuant to Article 11(2) RPBA in which the board gave its provisional opinion of the case oral proceedings were held on 25 September 2002 in which the appellant filed new claims 1 to 7 as his single request to grant a patent.
- IV. Claim 1 thereof reads as follows:
 - "1. A method of cleaning a hollow single-walled medical instrument, comprising the steps of:

providing a conduit (11) attached to a pump means (8) for providing a pulsed flow (12) of cleaning fluid,

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providing a tank (2) containing cleaning
fluid (3),

attaching the medical instrument to the conduit (11),

before or after the attaching step, immersing the medical instrument in the cleaning fluid (3) in the tank (2),

operating the pump means (8), thereby supplying the pulsed flow (12) of cleaning fluid to the interior (7) of the medical instrument, and

subsequently detaching the cleaned medical instrument from the conduit (11) and removing it from the tank (2),

wherein the fluid is pulsed by means of a piston pump and the method further comprises the step of, simultaneously with the supplying of the pulsed flow (12) of cleaning fluid, applying ultrasonic waves to the fluid inside the medical instrument along the entire length of the instrument, the cleaning action being effected through the combined action of the pulsed flow (12) of cleaning fluid and the ultrasonic waves, in which cavitation of the fluid inside the instrument is effective to loosen debris attached to the interior surface of the instrument, the debris being moved along the interior of the instrument by the pulses eventually to emerge from the instrument."

- V. With respect to this claim 1 the appellant essentially argued as follows:
 - a piston pump being used to provide a pulsed flow of cleaning fluid could produce pulses of rectangular form with an express time in which the cleaning fluid is at rest and no turbulances are

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present in the single-walled medical instrument to be cleaned;

- while the cleaning fluid is at rest the ultrasonic waves applied to the cleaning fluid were highly efficient to clean the inside surface of the medical instrument;
- the rectangular pulse form is achieved by the piston pump basically during its reverse stroke in which a negative pressure prevails in the system so that pumped fluid is brought to an immediate halt allowing the ultrasonic waves to displace any contaminants from the article to be cleaned;
- sharp pulses of cleaning fluid could not be derived from (D1) since the known switching valves only allow **gradual** pressure changes of the cleaning fluid;
- the claimed more defined flow of cleaning fluid was not rendered obvious by (D1) or
 - (D2) TW-A-236579 and its English Abstract and
 - (D3) DE-A-4 140 378

singly or in combination since (D2/D3) were not based on a pulsed flow of cleaning fluid or a piston pump therefore.

VI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the documents submitted during the oral proceedings, namely claims 1 to 7 and description pages 1 to 6, in

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combination with the drawing as originally filed.

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Amendments
- 2.1 Claim 1 is a method claim in contrast to originally filed claim 1 ("Apparatus for..."). In originally filed claim 16 a method of cleaning is however, disclosed so that there is a basis for the change of category.
- 2.2 Claim 1 contains all features of originally filed claim 1 plus features of originally filed claims 6 (piston pump), 7 (tank containing cleaning fluid), 14 (medical instrument), 15 (single walled instrument), and originally filed Figure 1 and its description so that claim 1 is not open to an objection under Article 123(2) EPC.
- 3. Novelty

From the nearest prior art document (D1) a **piston pump** is clearly not derivable so that claim 1 is novel, Article 54 EPC.

- 4. Inventive step
- 4.1 From (D1) a method of cleaning a hollow medical instrument is known in which according to its Figure 5b a pulsed flow of cleaning fluid is applied, see (solenoid) values "45, 47" and Figure 1, in combination with the application of ultrasonic waves, see reference

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signs "65" in Figure 1.

- 4.2 The appellant argued in a believable fashion that the pulses of cleaning fluid according to (D1) which are controlled by valves "45, 47", are inaccurate and do not lead to a clear differentiation of a "yes-" and "no-" application of a cleaning fluid pressure within the medical instrument to be cleaned by relying on ultrasonic waves. Since the existence of a moving cleaning fluid within a hollow article to be cleaned according to the appellant has to be seen as an obstacle to carrying out effective ultrasonic wave cleaning it is the object of the invention to render the method of cleaning a hollow medical instrument according to (D1) more effective.
- 4.3 The solution to this object is achieved with the features laid down in claim 1 which claim is not cast into a two-part form since this requirement is not compulsory with respect to a method claim.

The crucial features of claim 1 are that the hollow medical instrument is single-walled - in contrast to the disclosure of (D1), see for instance the double-walled endoscope according to its Figure 9 - and that the pulses of cleaning fluid applied to the medical instrument to be cleaned are delivered by a piston pump.

4.4 The replacement of a **double**-walled article to be cleaned by a **single**-walled article is clearly an obvious step to be carried out by a skilled person since for instance (D2) and (D3) - both documents relying on an internal and external cleaning fluid in combination with the application of ultrasonic waves -

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clearly deal with single-walled articles to be cleaned.

- 4.5 Claim 1 is, however, not only based on the provision of a single-walled article to be cleaned, but rather on a further feature namely the application of a piston pump as the means to create a pulsed flow of cleaning fluid which is not rendered obvious by the prior art to be considered (D1) to (D3) and which achieves an extra effect with respect for instance to (D1) as the nearest prior art document.
- 4.6 A piston pump is characterised by a forward and a reverse stroke and by at least two one-way valves, one on the entry and the other on the exit of the pump.
- 4.7 The appellant argued in a believable fashion that a piston pump achieves a sharper pulse form (i.e. a clear phase of pressure application and of decompression, or in other words a clear yes/no differentiation) since the reverse stroke of the piston leads primarily to a negative pressure and secondly to a quick closing of the one-way valve on the exit of the pump making the cleaning fluid in the medical instrument to be cleaned immediately pressureless and bringing the pulsed cleaning fluid to a clear halt in which the ultrasonic waves are highly efficient and not disturbed by any turbulances as is possibly the case in the subjectmatter of (D1) relying on valves to achieve a pulsed flow of cleaning fluid.
- 4.8 The board is in agreement with appellant's argument brought forward in the oral proceedings that a rectangular pulse form of the cleaning fluid and its outcome on the cleaning result is not to be seen from (D1) to (D3) even considered in combination since there

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cannot be seen any incentive to replace the valves used in (D1) to achieve a pulsed flow of cleaning fluid since it is believable that a skilled person before the presentation of the claimed invention was unaware of the importance of sharp pulses instead of pulses relying on gradually opening/closing valves as in (D1).

- (D2) being silent about the means to achieve a pulsed flow of cleaning fluid and (D3) disclosing a single-walled article to be cleaned, however, in combination without a pulsed flow of cleaning fluid, are only relevant by **hindsight**.
- 4.9 Summarizing the above considerations the subject-matter of claim 1 is not only novel but inventive within the meaning of Article 56 EPC so that this claim is allowable.
 - Claims 2 to 7 relating to embodiments of the teaching of claim 1 are likewise allowable as dependent claims.
- 4.10 The description with pages 1 to 6 handed over during the oral proceedings is consistent with the claims and meets the essential requirements of the EPC and can form the basis for grant in combination with the single figure originally filed.

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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 grant a patent with the following documents:
 - (1) Description pages 1 to 6 as filed during the oral proceedings held on 25 September 2002.
 - (2) Claims 1 to 7 as filed during the oral proceedings held on 25 September 2002.
 - (3) Figure 1 as originally filed.

The Registrar: The Chairman:

A. Counillon C. T. Wilson