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**Datasheet for the decision
of 11 June 2021**

Case Number: T 2828/18 - 3.2.08

Application Number: 12754885.7

Publication Number: 2683437

IPC: A61M25/10, A61B1/31, A61B1/018

Language of the proceedings: EN

Title of invention:
BALLOON-EQUIPPED ENDOSCOPIC DEVICES AND METHODS THEREOF

Applicant:
Smart Medical Systems Ltd.

Headword:

Relevant legal provisions:
EPC Art. 123(2), 84, 54, 56
RPBA 2020 Art. 13(1), 13(2)

Keyword:
Amendments - allowable (yes)
Claims - clarity (yes)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:



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Case Number: T 2828/18 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 11 June 2021

Appellant: Smart Medical Systems Ltd.
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 24 July 2018
refusing European patent application No.
12754885.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman M. Foulger
Members: A. Björklund
E. Mille

Summary of Facts and Submissions

I. The appeal was filed by the applicant (appellant) against the decision of the examining division to refuse the patent application.

The examining division decided that the subject-matter of claim 1 of the main request and the auxiliary requests I and II then on file was not novel in view of D5.

II. Oral proceedings by videoconference were held before the Board on 11 June 2021.

III. At the end of the oral proceedings, the appellant withdrew the then valid main and first auxiliary request and requested that the decision under appeal be set aside and that a patent be granted on the basis of the second auxiliary request filed during the oral proceedings.

IV. Claim 1 of the second auxiliary request filed during the oral proceedings reads as follows:

A "An endoscopy system comprising:
B' a balloon-equipped endoscope (100) including a balloon (110) which is configured for engagement with an interior wall of a patient's colon when inflated to a first engagement pressure; and
C a balloon inflation subsystem (130) operative to selectably inflate said balloon to said first engagement pressure;
wherein:

- D' the first engagement pressure is a slidable frictional engagement pressure, with the balloon (110) being configured for slidable frictional engagement with the interior wall of the patient's colon and axial stretching of said interior wall and to at least partially unfold natural folds of said interior wall when inflated to the slidable frictional engagement pressure and displaced axially along said patient's colon;
- E the balloon inflation subsystem is operative to inflate said balloon (110) to a second engagement pressure different from the first engagement pressure,
- E1' with the second engagement pressure being an anchoring pressure within a predetermined range of anchoring pressures, with the balloon (110) being configured for anchoring engagement with the interior wall of the patient's colon when inflated to the anchoring engagement pressure; and
- F the balloon inflation subsystem (130) comprises a user interface (400) configured to effect selection by an operator between the anchoring pressure and the slidable frictional engagement pressure, whereby switching between an anchoring state and a slidable frictional engagement pressure state of the balloon (110) is performable by an operator as needed during an endoscopy procedure;
characterized in that
- G said balloon inflation subsystem (130) is operative to automatically maintain inflation of said balloon (110) at said slidable frictional engagement pressure at various

balloon locations along the length of said patient's colon, notwithstanding variations in the cross sectional area of said patient's colon at such locations."

The feature designations have been added by the Board.

V. The following document is relevant to the decision:

D5: EP 1 656 879 A2

VI. The appellant's arguments can be summarised as follows:

Admittance of the second auxiliary request filed with letter of 3 June 2021

This request was filed in response to the objection under Article 123(2) EPC which was raised for the first time in the Board's communication. It should therefore be admitted into the proceedings.

Amendments

Claim 1 of the second auxiliary request filed with letter of 3 June 2021, respectively during the oral proceedings, was based on claims 1, 4, 9 and 26, description page 33, line 26 to page 34, line 6, page 38, lines 27 to 29, page 38, line 30 to page 39, line 2 as originally filed.

The dependent claims had a basis in originally filed dependent claims 2, 5 to 8, 13, 16 to 19, 21 and 24.

Clarity

It would be a routine matter for the skilled person to set the apparatus parameters to achieve the frictional slidable frictional engagement pressure and the anchoring pressure and they would have no difficulty whatsoever in determining whether or not a balloon inflation subsystem was operative to to inflate the ballon to the required pressures.

A meaningful definition of the actual pressure ranges which would apply to all ballon fabrics and shapes would be very difficult and would unduly restrict the scope of protection. A definition of the endoscope system by functional features was therefore appropriate.

The requirements of Article 84 EPC were thus fulfilled.

Novelty

The subject-matter of claim 1 differed from the endoscope system of D5 at least in feature G. It was therefore new in the sense of Article 54(1) and (2) EPC.

Inventive step

Feature G solved the problem of providing an endoscopy system which improved the accuracy of the endoscopic procedure.

D5 did not disclose that the endoscope was to be moved relative to the colon with the balloon in an inflated state where it would engage the colon. The skilled person would therefore have no reason to modify the inflation subsystem such that it would automatically maintain inflation of the balloon at a frictional

engagement pressure at various locations along the length of the colon, notwithstanding variations in the cross sectional area of the patient's colon as defined in feature G.

The subject-matter of claim 1 therefore involved an inventive step, Article 56 EPC.

Reasons for the Decision

1. Admittance of the amended second auxiliary requests.

1.1 The appellant filed a new second auxiliary request with letter of 3 June in response to the objection under Article 123(2) EPC which the Board raised in its communication.

The appellant filed the request at the earliest possibility after the objection had been raised. The Board thus decided to admit this request into the proceedings (Article 13(1) RPBA 2020).

1.2 The appellant filed a further amended second auxiliary request in the oral proceedings.

This request was filed in response to the Board's objection that the two-part form of claim 1 was incorrect - contrary to the requirements of Rule 29(2) EPC - which was raised for the first time in the oral proceedings.

These are exceptional circumstances under which the Board decided to admit the second auxiliary request filed during the oral proceedings into the appeal proceedings (Article 13(2) RPBA 2020).

2. Amendments

Claim 1 of the second auxiliary request filed during the oral proceedings is based on claims 1, 4, 9 and 26, description page 33, line 26 to page 34, line 6, page 38, lines 27 to 29, page 38, line 30 to page 39, line 2 as originally filed.

The dependent claims have a basis in originally filed dependent claims 2, 5 to 8, 13, 16 to 19, 21 and 24.

The requirements of Article 123(2) EPC are therefore fulfilled.

3. Clarity

The subject-matter of claim 1 is partly defined by functional features.

However, defining the specific pressure ranges of the slidable frictional engagement pressure and the anchoring pressure would also require that the material, the geometry and the surface characteristics of the balloon would be defined in the claim. The scope of the claim would thus be unduly limited.

Furthermore, the skilled person would have no problem in determining whether an endoscope is operable to perform the functions defined in the claim and thus to determine the scope of the claim.

The subject-matter of claim 1 therefore fulfills the requirements of Article 84 EPC.

4. Novelty

The endoscope of Figures 1 to 5 of D5 has a balloon 60 and an inflation subsystem 100 (paragraph [0027]) which can change the pressure in the balloon from a deflated state where the pressure is below atmospheric pressure and the balloon is in a shrunk state (paragraphs [0036], [0040] and [0048]) to an anchoring pressure where the endoscope cannot be moved relative to the colon (paragraph [0038]). The inflation system is controlled via a hand switch 104 (paragraph [0027]) and the pressure of the balloon is indicated on display 106 of the inflation system (paragraph [0028]). It is further possible to pause an inflation or deflation procedure (paragraphs [0084] and [0085]) at an intermediary pressure where the balloon would engage with the interior wall of the colon while not being anchored thereto.

The balloon inflation subsystem of the endoscope system of D1 is however not operative to automatically maintain this intermediate pressure, should the balloon be moved to a position of the colon with a different cross sectional area.

The subject-matter of claim 1 therefore differs from the endoscope system in D5 in feature G and is thus new (Article 54(1) and (2) EPC).

5. Inventive step

The technical problem solved by feature G is to provide an endoscopy system which improves the accuracy of the endoscopic procedure.

D5 does not mention that the balloon could be inflated to an intermediate pressure such that it contacts the

colon when the endoscope is moved along the colon. It rather describes that the balloon 60 is deflated when the endoscope 12 is moved, see paragraphs [0036] to [0041] in conjunction with Figures 4A to 4H.

Since the endoscope of D5 is not intended to be moved along the colon with the balloon in an inflated state, the skilled person would have no reason to modify the inflation subsystem of the endoscopy system of D5 such that it could automatically maintain a slidable frictional engagement pressure as defined in feature G.

The subject-matter of claim 1 therefore involves an inventive step.

Order

For these reasons it is decided that:

The decision under appeal is set aside and the case remitted to the first instance with the order to grant a patent based on claims 1 to 13 of the amended second auxiliary request, pages 1-41 of the amended description submitted by the appellant during the oral proceedings and figures 1-14 as published.

The Registrar:

The Chairman:



C. Moser

M. Foulger

Decision electronically authenticated