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**Datasheet for the decision  
of 16 May 2013**

**Case Number:** T 1932/09 - 3.2.02

**Application Number:** 01912088.0

**Publication Number:** 1263318

**IPC:** A61B 5/05, H04L 25/49

**Language of the proceedings:** EN

**Title of invention:**

A device and system for in vivo imaging

**Applicant:**

Given Imaging Ltd.

**Headword:**

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**Relevant legal provisions:**

EPC Art. 56

RPBA Art. 13(1)

**Keyword:**

"Inventive step (no, main and first to third auxiliary requests)"

"Admissibility (no; fourth auxiliary request)"

**Decisions cited:**

T 0230/01

**Catchword:**

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Case Number: T 1932/09 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 16 May 2013

**Appellant:** Given Imaging Ltd.  
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**Representative:** HOFFMANN EITLE  
Patent- und Rechtsanwälte  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 23 April 2009  
refusing European patent application  
No. 01912088.0 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman:** E. Dufrasne  
**Members:** M. Stern  
D. Ceccarelli

## **Summary of Facts and Submissions**

- I. The applicant lodged an appeal against the decision of the Examining Division dispatched on 23 April 2009 refusing European application No. 01 912 088.0 on the ground of lack of inventive step over the following documents:
- D7: DE-A-34 40 177  
D2: EP-A-0 941 691.
- II. Notice of appeal was received on 27 May 2009 and the fee for appeal was paid on that same day. The statement setting out the grounds of appeal was received on 3 September 2009.
- III. In its provisional opinion dated 11 February 2013 annexed to the summons to oral proceedings, the Board raised doubts about compliance with Articles 123(2) and 84 EPC and the inventiveness of the claimed subject-matter.
- IV. Oral proceedings were held on 16 May 2013.
- V. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with letter dated 3 September 2009 or, in the alternative, of one of the first to third auxiliary requests filed with letter dated 16 April 2013, or of the fourth auxiliary request filed during the oral proceedings.

VI. Claim 1 of the different requests reads as follows  
(deletions from the main request are struck through,  
additions are underlined):

**Main request:**

"1. A swallowable capsule (10) for in vivo imaging of the gastrointestinal tract, said capsule (10) comprising an optical window (21), the capsule comprising:  
at least one CMOS imaging camera (24);  
two illumination sources (23) for illuminating a gastrointestinal tract site;  
an optical system (22) co-planar with said illumination sources (23) for imaging the gastrointestinal tract site onto the CMOS imaging camera (24), the optical system (22) being separated from the optical window (21), the CMOS imaging camera (24) imaging the site via the optical window (21) and via the optical system (22), and the illumination sources (23) being disposed on either side of said optical system (22) and illuminating the site directly via the optical window (21) and not via the optical system (22); and  
a transmitter (26) for transmitting an output of the CMOS imaging camera (24)."

**First auxiliary request:**

"1. A swallowable capsule (10) for in vivo imaging of the gastrointestinal tract, said capsule (10) comprising an optical window (21), the capsule comprising:  
~~at least one~~ CMOS imaging camera (24);

two illumination sources (23) for illuminating a gastrointestinal tract site;  
an optical system (22) co-planar with said illumination sources (23) for imaging the gastrointestinal tract site onto the CMOS imaging camera (24), the optical system (22) being separated from the optical window (21), the CMOS imaging camera (24) imaging the site via the optical window (21) and via the optical system (22), and the illumination sources (23) being disposed on either side of said optical system (22) and illuminating the site directly via the optical window (21) and not via the optical system (22); and  
a transmitter (26) for transmitting an output of the CMOS imaging camera (24)."

***Second auxiliary request:***

"1. A swallowable capsule (10) for in vivo imaging of the gastrointestinal tract, said capsule (10) comprising an optical window (21), the capsule comprising:  
~~at least one~~ CMOS imaging camera (24);  
two illumination sources (23) for illuminating a gastrointestinal tract site;  
an optical system (22) co-planar with said illumination sources (23) for imaging the gastrointestinal tract site onto the CMOS imaging camera (24), the optical system (22) being separated from the optical window (21), the CMOS imaging camera (24) imaging the site via the optical window (21) and via the optical system (22), and the illumination sources (23) being disposed ~~on either side of~~ around said optical system (22) and illuminating the site directly via the optical window (21) ~~and not via the optical system (22)~~; and

a transmitter (26) for transmitting an output of the CMOS imaging camera (24)."

***Third auxiliary request:***

"1. A swallowable capsule (10) for in vivo imaging of the gastrointestinal tract, said capsule (10) comprising an optical window (21), the capsule comprising:  
~~at least one~~ CMOS imaging camera (24);  
two illumination sources (23) for illuminating a gastrointestinal tract site;  
an optical system (22) ~~co-planar with said illumination sources (23)~~ for imaging the gastrointestinal tract site onto the CMOS imaging camera (24), the optical system (22) being separated from the optical window (21), the CMOS imaging camera (24) imaging the site via the optical window (21) and via the optical system (22), and the illumination sources (23) being disposed ~~on either side of~~ around said optical system (22) and illuminating the site directly via the optical window (21) ~~and not via the optical system (22)~~; and  
a transmitter (26) for transmitting an output of the CMOS imaging camera (24)."

***Fourth auxiliary request:***

"1. A swallowable capsule (10) for in vivo imaging of the gastrointestinal tract, said capsule (10) comprising an dome shaped optical window (21), the capsule comprising:  
~~at least one~~ CMOS imaging camera (24);  
two illumination sources (23) for illuminating a gastrointestinal tract site;

an optical system (22) ~~co-planar with said illumination sources (23)~~ for imaging the gastrointestinal tract site onto the CMOS imaging camera (24), the optical system (22) being separated from the optical window (21), where the CMOS imaging camera (24) and the illumination sources (23) are positioned in the proximity of the focal plane of the shape defined by the optical dome, the CMOS imaging camera (24) imaging the site via the optical window (21) and via the optical system (22), and the illumination sources (23) being disposed ~~on either side of~~ around said optical system (22) and illuminating the site directly via the optical window (21) ~~and not via the optical system (22)~~; and a transmitter (26) for transmitting an output of the CMOS imaging camera (24)."

VII. The arguments of the appellant are summarised as follows:

(i) *Inventive step*

- D7 did not provide the skilled person with an enabling disclosure, and could not be considered as the closest prior art. From the information provided in D7 and the skilled person's common general knowledge it was impossible to control the rotation of the capsule with an external magnetic field and to determine its rotational and translational positions precisely enough to create a meaningful image. Moreover, the device only produced completely dark image points devoid of any information. The skilled person would also not know how to construct a freely rotatable inner housing within an outer shell as disclosed on page 13, lines 1 to 5 of

D7. At the oral proceedings the appellant accepted that it was physically possible to construct the device disclosed in D7, but took the view that its information was insufficient to render the device workable for imaging the intestine.

- Since the appellant had given plausible arguments that the common general knowledge combined with the description of D7 was not sufficient to implement a working system that provided meaningful images from inside the human body, it was the duty of the EPO to provide proof that the common general knowledge enabled the construction of a working endoscope according to D7.

- Even if D7 was considered to provide an enabling disclosure, the recording device A inside the capsule of D7 could not be considered to be an imaging camera within the established meaning of the term, because it imaged only a single point. The device A was a photodiode imaging sensor which provided electrical signals from which an image was eventually constructed. The capsule as a whole was considered to be a camera. Moreover, it was not reasonable to assume that the skilled person would want to replace the simple photo-detector A in D7, which sequentially recorded individual points in correlation with a rotational image pick-up, by a CMOS imager as disclosed in D2 in which a plurality of image points was imaged simultaneously.

- Furthermore, in D7 the optical lens A2 was not separated from the optical window. As a result the image points were always dark. Moreover, in D7, the



light sources G1 and G2 were clearly well removed from whatever plane passed through lens A2, whereby the light sources and the lens could not be said to be "coplanar", an expression which meant that these three-dimensional objects were so arranged that a common plane connected all of them.

- Therefore, the capsule as defined in claim 1 of any of the main and first to third auxiliary requests was based on an inventive step.

*(ii) Admissibility of the fourth auxiliary request*

The fourth auxiliary request had been filed late as a last attempt to overcome the objection of lack of inventive step. Its subject-matter was taken word for word from page 8, lines 14 to 18 of the description, and was not so complex that it could not be dealt with without adjourning the oral proceedings.

**Reasons for the Decision**

1. The appeal is admissible.
2. *Inventive step - main and first to third auxiliary requests*
  - 2.1 Document D7 is considered as the closest prior art. D7 discloses a swallowable capsule for in vivo imaging of the gastrointestinal tract (page 7, first paragraph; page 8, lines 13 to 23) comprising an imaging sensor (A; page 13, lines 26 to 31; page 14, last paragraph; page 16, lines 26 to 32), two light sources (G1, G2;

page 13, lines 33 to 37), a focussing lens (A2) for imaging the gastrointestinal tract site onto the imaging sensor (page 13, lines 26 to 30), and a transmitter (S) for transmitting an output of the imaging sensor (page 14, lines 14 to 20).

Contrary to the view held by the appellant, the lens A2 is separated from the optical window H (page 12, line 37 to page 13, line 8). Moreover, from Figure 1 of D7 it can be seen that the light sources G1, G2 are placed "on either side" (or "around") the lens A2, and that the light sources illuminate the site directly via the optical window H and not via the lens A2.

Furthermore, since the light sources G1, G2 and the lens A2 are contained within the plane of Figure 1, they are to be considered as being "co-planar" in the sense the appellant attributes to the term for three-dimensional objects, namely an arrangement of objects such that there is a plane that connects all of the objects.

D7 mentions moreover that the imaging sensor A may comprise a photodiode or any similar sensor (page 13, line 27), and that the imaging sensor A may also be a multi-point linear array sensor (page 16, lines 26 to 32). D7 is however silent as to the specific type of photodiode sensor technology to be used.

- 2.2 Consequently, the swallowable capsule of claim 1 of the main and first to third auxiliary requests differs from that of D7 in that the capsule comprises a CMOS imaging camera.

- 2.3 Hence, when attempting to reduce the capsule of D7 to practice the skilled person needs to solve the objective technical problem of finding a suitable imaging photodiode sensor for endoscopic imaging.
- 2.4 Document D2 discloses a large variety of endoscopic imaging devices (see paragraph [0034]) utilising as an imaging sensor a photodiode-based CMOS imaging chip, or CMOS imaging camera (note that in paragraphs [0036] and [0037], the terms "chip" and "camera" are both used interchangeably). D2 explains that such an imaging camera has the benefit of being very compact and having low power requirements (column 8, lines 9 to 15 and 22 to 24). These are in fact the same technical effects which the application aims to achieve by using a CMOS imaging camera (see page 1, lines 12 to 14 of the application).
- 2.5 Hence, the skilled person faced with the problem of reducing to practice the capsule of D7 would readily consider the teaching of D2 and thus devise the imaging sensor of D7 (in particular in its embodiment as a linear array) as a CMOS imaging camera. Thereby, the skilled person would arrive at the claimed subject-matter without exercise of an inventive step.
- 2.6 In its first line of argument, the appellant argued that D7 did not provide the skilled person with an enabling disclosure, so that D7 should not be considered as the closest prior art.
- 2.6.1 According to Article 54(2) EPC, "the state of the art" comprises "everything made available to the public by means of a written or oral description, by use, or in

any other way, before the date of filing of the European patent application". It is established jurisprudence (see e.g. T 230/01, Reasons point 5.2, and decisions cited therein) that a document normally forms part of the state of the art, even if its disclosure is deficient, unless it can unequivocally be proven that the disclosure of the document is not enabling, or that the literal disclosure of the document is manifestly erroneous and does not represent the intended technical reality. Such a non-enabling or erroneous disclosure should then not be considered part of the state of the art.

2.6.2 At the oral proceedings the appellant no longer disputed that it was physically possible to construct the device disclosed in D7, but it was alleged that D7 contained insufficient information to render the device workable for imaging the intestine. In this respect, the appellant mainly contended that it was impossible to control the rotation of the capsule with an external magnetic field and to determine its rotational and translational positions *in a sufficiently precise way* to create a meaningful image.

The Board finds however that document D7 in fact basically discloses how the capsule is rotationally and axially moved in an external magnetic field controlled by three orthogonal coils (page 17, lines 7 to 36), and it also discloses how the position of the capsule is determined using three orthogonal dipoles in the capsule (page 18, lines 1 to 19). Therefore, in the Board's view, the alleged insufficient precision or quality of the produced image as perceived by the

appellant falls short of unequivocally proving the alleged speculative nature of D7.

The Board considers moreover that since the illumination sources in D7 are provided precisely for illuminating the site of the intestinal wall being imaged, the appellant's allegation that the device in practice only produced completely dark image points is unconvincing. In the absence of any further convincing argument or evidence, the Board could also not accept the appellant's initial allegation that the skilled person would not know how to construct the capsule with a freely rotatable inner housing within the outer shell H as disclosed in D7 on page 13, lines 1 to 5. At the oral proceedings the appellant did indeed accept that it was physically possible to construct the device disclosed in D7 (but not with the necessary image precision, as discussed above).

- 2.6.3 The Board consequently finds that the appellant's submissions do not contain sufficient evidence to unequivocally prove that D7 is indeed speculative, i.e. not enabling. It is thus not incumbent on the EPO to prove the contrary of what the appellant has merely alleged.

The Board thus reaches the conclusion that document D7 is to be taken into consideration as the closest prior art.

- 2.7 In a second line of argument, the appellant argued that the recording device A in D7 was not to be considered as an imaging camera within the established meaning of the term because it imaged only a single point.

The Board finds that this argument is not directly relevant to the problem-solution approach as presented above, which is based on the assessment that the device A in D7 is a photodiode imaging sensor which provides electrical signals from which an image is eventually constructed. The appellant accepted this assessment during the oral proceedings.

- 2.8 Lastly, the appellant argued that it was not reasonable to assume that the skilled person would want to replace the simple photo-detector A in D7, which sequentially recorded individual points in correlation with a rotational image pick-up, by a CMOS imager as disclosed in D2 in which a plurality of image points was imaged simultaneously.

The Board is not convinced by this argument either. Departing from D7, the skilled person trying to solve the aforementioned problem will naturally choose the most appropriate imaging sensor technology for the imaging sensor A (in particular in its embodiment as a linear array imaging sensor), irrespective of the rotational movement to which it is subjected for scanning the intestinal wall. There is no incompatibility with the implementation of such a rotating imaging sensor using the CMOS technology taught by D2 (mentioned under point 2.4 above).

- 2.9 For the reasons given above, the subject-matter of claim 1 of the main and first to third auxiliary requests lacks an inventive step within the meaning of Article 56 EPC.

As a consequence, the Board does not find it necessary to deal with the objections under Articles 123(2) and 84 EPC raised in the communication annexed to the summons to oral proceedings.

3. *Admissibility of the fourth auxiliary request*

3.1 The fourth auxiliary request was filed during the oral proceedings in an attempt to overcome the objection of lack of inventive step.

3.2 It is the established jurisprudence of the boards of appeal that the appeal procedure is designed to ensure that the proceedings are as brief and concentrated as possible and ready for decision at the conclusion of oral proceedings. Therefore, amendments to the claims must be filed at the earliest possible moment and the Board may disregard amended claims if they are not submitted in good time prior to oral proceedings ("Case Law of the Boards of Appeal", 6th edition 2010, VII.E. 16.3.1). This practice corresponds to Article 13(1) RPBA, which gives a Board the discretion to admit and consider new requests presented by an appellant after it has filed its grounds of appeal. The Board must exercise that discretion in view inter alia of the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

With regard to procedural economy, the factors to be examined in deciding whether a late-filed request is admissible include whether the subject-matter of the new claim is so clear and straightforward that it can be understood and allowed without further discussion

("Case Law of the Boards of Appeal", 6th edition 2010, VII.E.16.4.1).

3.3 In the present case the Board considered, in a prima facie assessment, that the amendments made to claim 1 were not clearly compliant with Articles 123(2) and 84 EPC. Whilst the appellant indicated that the amendments were taken word for word from page 8, lines 14 to 18 of the description, the Board firstly failed to see that the claimed features also included the limitation to the *ellipsoidal* shape of the optical window as disclosed in the mentioned passage. The Board was unable, moreover, to immediately discern the meaning of the ambiguous expression "*the proximity of the focal plane of the shape defined by the optical dome*", in particular since it was not immediately clear what "*the focal plane*" of an optical dome would be (even if its shape had been defined as ellipsoidal).

3.4 The Board consequently decides that the fourth auxiliary request is not admissible under Article 13(1) RPBA.



**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

D. Hampe

E. Dufrasne