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**Datasheet for the decision
of 11 November 2015**

Case Number: T 0475/12 - 3.2.02

Application Number: 06700046.3

Publication Number: 1835854

IPC: A61B5/05, A61B1/00

Language of the proceedings: EN

Title of invention:

DEVICE, SYSTEM AND METHOD FOR IN-VIVO EXAMINATION

Applicant:

Given Imaging Ltd.

Headword:

Relevant legal provisions:

EPC Art. 53(c), 84

Keyword:

Exceptions to patentability -
method for treatment by therapy (yes)
Claims - clarity (no)

Decisions cited:

G 0001/03, G 0001/04, G 0001/07, T 0290/86, T 0820/92,
T 0067/02, T 1695/07, T 1635/09

Catchword:



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Case Number: T 0475/12 - 3.2.02

**D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 November 2015**

Appellant: Given Imaging Ltd.
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 18 October 2011
refusing European patent application No.
06700046.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman E. Dufrasne
Members: C. Körber
M. Stern

Summary of Facts and Submissions

- I. On 18 October 2011 the Examining Division posted its decision to refuse European patent application No. 06700046.3 under Articles 123(2), 53(c) and 84 EPC.
- II. An appeal was lodged against this decision by the applicant by notice received on 23 December 2011, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 14 February 2012.
- III. By communication of 23 July 2015, the Board summoned the appellant to oral proceedings and forwarded its provisional opinion.
- IV. With letter dated 9 October 2015 the appellant submitted further arguments and amended versions of the main request and the first, second and third auxiliary requests filed with the statement of grounds of appeal.
- V. Oral proceedings were held on 11 November 2015. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of main request, or, in the alternative, one of the first to third auxiliary requests, all filed with letter dated 14 February 2012, or one of the main request and the first to third auxiliary requests in amended version, all filed with letter dated 9 October 2015.
- VI. Claims 1, 7, 9 and 10 of the **main request** read:
- "1. A method for an in vivo examination, the method comprising:
substantially emptying (101) a subject's colon from content by administering a laxative to the subject;

subsequent to said emptying (101), the subject swallowing (102) a swallowable in-vivo imaging device (140); subsequent to said swallowing (102), the subject taking a booster laxative; and receiving (103) images transmitted from said imaging device (140)."

"7. The method according to one of claims 1 to 6 wherein emptying a subject's colon comprises ingesting laxatives and stimulants."

"9. The method of one of claims 1 to 8, comprising releasing a stored laxative and/or a stored stimulant stored in said imaging device (140) when said imaging device reaches a predefined area of a body lumen of said subject."

"10. The method of one of claims 1 to 9, wherein substantially emptying a subject's colon from content comprises waiting a pre-defined time-period after administering the laxative to the subject, and then administering to the subject a prokinetic agent."

Claims 2 to 6 and 8 are further dependent claims.

Claim 1 of the **first auxiliary request** reads:

"A method for an in vivo examination, the method comprising:
substantially emptying (101) a subject's colon from content by administering a laxative to the subject;
subsequent to said emptying (101), the subject swallowing (102) a swallowable in-vivo imaging device (140); and
receiving (103) images transmitted from said imaging device (140)."

Claims 5, 7 and 8 correspond to claims 7, 9 and 10 of the main request, respectively, with adapted dependencies and reference numeral 140 being deleted from claim 9. Claims 2 to 4 and 6 are further dependent claims.

Claim 1 of the **second auxiliary request** reads:

"A method for an in vivo examination, the method comprising:
substantially emptying (101) a subject's colon from content, including intake of a laxative by the subject; administering to the subject a prokinetic agent; the subject swallowing (102) a swallowable in-vivo imaging device (140), where the operation of emptying the colon is performed prior to the swallowing; and receiving (103) images transmitted from said imaging device (140)."

Claims 5, 7 and 8 correspond to claims 7, 9 and 10 of the main request, respectively, with adapted dependencies and reference numeral 140 being deleted from claim 9. Claims 2 to 4 and 6 are further dependent claims.

Claim 1 of the **third auxiliary request** reads:

"A method for an in vivo examination, the method comprising:
substantially emptying a subject's colon from content by administering a laxative to the subject, waiting a pre-defined time-period, and administering to the subject a prokinetic agent;
the subject swallowing a swallowable in-vivo imaging device after waiting a further pre-defined time period;

the subject subsequently taking a booster laxative; and receiving images transmitted from said imaging device."

Claims 7 and 9 correspond to claims 7 and 9 of the main request, respectively, with reference numeral 140 being deleted from claim 9. Claims 2 to 6 and 8 are further dependent claims.

The claims of the amended versions of the main request and the first, second and third auxiliary requests correspond respectively to the above-cited sets of claims, with the term "non-therapeutic" inserted before the word "method" at the beginning of claim 1.

VII. The appellant's arguments are summarised as follows:

The claimed method according to all requests was restricted to being a method of examination. A method of examination was not a method of treatment. Treatment implied some form of interaction with the human or animal body in order to obtain a physiological effect that had some kind of curative effect, e.g. combatting a pathological condition or excising pathological material. A method of examination involved no treatment whatsoever, as its goal was simply to obtain information, but not in any way to affect (i.e. treat) the body under examination with respect to combatting disease or alleviating symptoms. Method steps were generally limited by their purpose. As a consequence, in order for a step to be considered therapeutic, it had to have a purpose that was intended to be therapeutic. None of the steps of the claimed methods was intended to be therapeutic in the above-described sense, as they did not aim to alleviate any symptoms or pains, but simply served to enable a better collection of data through the in-vivo imaging device. As a

consequence, the overall method was directed towards obtaining information and none of the steps fell outside that basic purpose.

From section 2.2.2 of the impugned decision it appeared that the Examining Division believed that the emptying of the bowels with the help of laxative encompassed a therapeutic effect, since this effect would occur in patients who had a disorder, such as constipation. A further possible effect was that the measure could relieve, reduce or shorten the duration of pain caused by objects stuck in the gastrointestinal system. The Examining Division appeared to believe that if a method step had a potential therapeutic effect (although such an effect was not claimed) that would appear only in certain circumstances, but not in others, then this already rendered the method step therapeutic, and consequently the entire method therapeutic. The Examining Division's analysis contradicted the principle that methods were limited by their purposes.

It was clearly not the intention of Article 53(c) EPC to exclude from patentability all methods that comprised a single step that under undescribed conditions might have an effect that some people considered therapeutic in some uses of the methods. As stated in section 3.4.2.3 of G 1/07, the purpose of Article 53(c) was that "*the exclusion serves the purpose of, in the interest[s] of public health and of patients, specifically freeing the medical profession from constraints which would be imposed on them by patents granted on methods for surgical or therapeutic treatment*". The claimed method did not intend to therapeutically improve a patient's health, and consequently did not in any way interfere with the therapeutic freedom of medical professionals.

From sections 3.4.2.2 and 3.4.2.3 of G 1/07 it could be derived that methods for retrieving data useful for diagnosis were not automatically exempt from patentability simply because they required administering an agent to a patient, and that the exclusion was to be treated realistically and not formalistically, and especially in view of the purpose of the exclusion in the interest of public health. Even if a method step had to be seen as having some kind of surgical or therapeutic effect, it had to be asked what the health risks were and whether the protection of the medical profession required excluding methods comprising such steps from patentability. Something as uncritical and minor as administering a laxative could certainly not be seen as constituting a therapeutic step. The use of such a step within a method that had no therapeutic purpose could definitely not be seen as falling under the exception of Article 53(c) EPC. Since the claimed method had no therapeutic purpose or context, and since all method steps were completely harmless and uncritical, it had to be concluded that it was not the purpose of Article 53(c) to except such methods for in-vivo examination from patentability.

With the amended versions of the main request and the first to third auxiliary requests, therapy was explicitly disclaimed, in accordance with G 1/03 and section 4.2.2 of G 1/07.

Reasons for the Decision

1. The appeal is admissible.
2. Methods of treatment by therapy

2.1 Main request

Claim 1 comprises the steps of substantially emptying a subject's colon from content by administering a laxative to the subject and the subject taking a booster laxative.

Claim 7 comprises the step of ingesting laxatives and stimulants.

Claim 9 comprises the step of releasing a stored laxative and/or a stored stimulant stored in the imaging device when it reaches a predefined area of a body lumen of the subject.

Claim 10 comprises the step of administering to the subject a prokinetic agent.

Numerous examples of laxatives are indicated in the description at page 3, lines 6 to 10, e.g. SoffodexTM or MerokenTM. From lines 26 to 29 of page 9, lines 16 to 17 of page 10 and the sentence bridging pages 10 and 11 it can be derived that the term "booster laxative" is to be understood as an additional dose of laxative.

Examples of stimulants are mentioned in lines 11 to 12 of page 3, e.g. BisacodylTM. Examples of prokinetics are listed in the next two lines, e.g. TegaserodTM or DomperidoneTM.

These (booster) laxatives, stimulants and prokinetic agents are pharmaceutically active substances. When administered to the human body, they interact with the body and cause certain reactions, e.g. encouragement of bowel movements or increase of muscle contractions, as mentioned in lines 24 to 25 of page 7. Accordingly, certain physiological functions are altered. These

effects occur inevitably when the substances are administered to the body, irrespectively of whether or not they are explicitly mentioned in the claim wording.

The induced bowel movements and muscle contractions promote the emptying of the bowels. As mentioned in lines 12 to 14 of page 10, this may, at the initial stage before the imaging device is swallowed, constitute a mere colon-cleansing procedure. It is clear that such cleansing is necessary and desired before the imaging device is swallowed. Depending on the state of health of the "subject" to whom the laxative is administered, this procedure may have further (desired or undesired) effects. If the subject is for instance a patient suffering from constipation, the administration of a laxative effects a curative treatment of this disorder and thus constitutes a therapeutic step, as correctly observed by the Examining Division. Moreover, the induced emptying of the bowels results in a loss of essential electrolytes. In order to prophylactically counteract the danger of an electrolyte deficiency, most laxatives also comprise electrolytes. For instance, the laxative MerokenTM serves inter alia as an electrolyte replenisher for the treatment of hypokalemia (it is noted that the administration of substances counteracting negative side effects of a method, itself non-therapeutic, was nevertheless found to be prophylactic and thus therapeutic in T 820/92). Stimulants and prokinetic agents are also used to treat certain diseases or disorders, e.g. BisacodylTM for managing neurogenetic bowel dysfunction or DomperidonTM serving as an antiemetic. If the subject suffers from any of these disorders, the administration of these pharmaceuticals necessarily has a therapeutic effect. On the other hand, there may also be negative side-effects, as is

the case with most pharmaceuticals. In order to assure an adequate analysis of the underlying benefits and risks, these substances usually have to be prescribed by a medical doctor.

Accordingly, the administration of laxatives, stimulants or prokinetics has a cleansing effect, which may be non-therapeutic, as well as certain therapeutic effects, as mentioned above, depending on the health state of the subject to which they are administered. The Board does not consider it possible as a matter of law to draw a distinction between applying these method steps to a possibly healthy subject as opposed to a patient suffering from a disorder that is treatable using these substances. According to established jurisprudence as cited in "Case Law of the Boards of Appeal of the EPO", 7th edition 2013, I.B.4.4.2, if the scope defined by the wording of the claim encompasses a use comprising a non-therapeutic element which is inseparably associated with a therapeutic element, the method is non-patentable under Article 53(c) EPC. The present situation is in particular comparable to the case underlying T 290/86, where it was found that the use of a certain composition for cleaning plaque and/or stains from human teeth inevitably had a therapeutic as well as a cosmetic effect (point 3.2).

A further aspect of the claimed method is that the above-mentioned substances are not only administered for cleansing purposes before the imaging device is swallowed, but also in order to propel the device once it is within the colon (page 2, lines 11 to 13 and page 10, lines 12 to 14). As long as the imaging device remains within the gastro-intestinal tract of the subject, it constitutes a foreign object within the subject's body. This represents a non-physiological

condition. As conceded by the appellant, there is even the risk that the device is not egested naturally at all ("capsule retention"). Even though this risk seems to be relatively low, it represents a major complication, requiring endoscopic or even conventional surgical intervention. By promoting propulsion of the imaging device in the gastro-intestinal tract, the above-mentioned substances also have a prophylactic effect in that they contribute to avoiding a pathological situation, viz. the device's retention in the subject's body after swallowing. It is established jurisprudence as cited in "Case Law of the Boards of Appeal of the EPO", 7th edition 2013, I.B.4.4.1a that a prophylactic treatment aimed at maintaining health by preventing ill effects that would otherwise arise amounts to a method of treatment by therapy.

The above-mentioned therapeutic effects are inevitably associated with the claimed administration of the respective substances. It is not necessary that these effects be explicitly mentioned in the claim for its subject-matter to fall under the exception clause. Also, the stated overall purpose of the claimed method, i.e. "in vivo examination", is not decisive if one of its features constitutes a step for treatment by therapy, which is the case here as explained above. As stated in point 6.2.1 of the reasons of opinion G 1/04, and explicitly confirmed in point 3.2.5 of decision G 1/07, a claim comprising one single therapeutic step falls under the exception clause of Article 53(c) EPC.

Referring to points 3.4.2.2 and 3.4.2.3 of G 1/07, the appellant argued that something as "uncritical and minor" as administering a laxative could certainly not be seen as constituting a therapeutic step. The cited passages belong to the introductory part of section

3.4.2 entitled "*Interventions being 'treatment by surgery' by their nature*", where certain criteria regarding the definition of term "treatment by surgery" are set out subsequently in points 3.4.2.4 et seq. The reference to "uncritical methods involving only a minor intervention" in point 3.4.2.3 must hence be seen in the context of treatments by surgery (where the nature of the intervention plays a decisive role) and cannot be simply transposed to methods of treatment by therapy. In this latter respect, criteria such as "uncritical" or "minor" are not applicable - what is decisive is whether a therapeutic effect is achieved by the administered substance in the recipient's body.

Since the above-mentioned steps in independent claim 1 as well as those of dependent claims 7, 9 and 10 constitute steps for treatment by therapy, their subject-matter is excepted from patentability under Article 53(c) EPC. Under these circumstances it is not necessary for the Board to decide if the claimed method possibly also comprises or encompasses steps for treatment of the human body by surgery.

2.2 First to third auxiliary requests

Claim 1 of the first auxiliary request comprises the step of administering a laxative to the subject. Claim 1 of the second auxiliary request comprises the steps of intake of a laxative by the subject and administering to the subject a prokinetic agent. Claim 1 of the third auxiliary request comprises the steps of administering a laxative and a prokinetic agent to the subject and the subject subsequently taking a booster laxative. The dependent claims of the auxiliary requests correspond to those of the main request as indicated above in section VIII. Since the

sets of claims according to the first to third auxiliary requests thus all comprise several of the steps for treatment by therapy comprised in the main request, their subject-matter is also excepted from patentability under Article 53(c) EPC.

3. Clarity - amended versions of the main request and first to third auxiliary requests

The amended versions of the claims of the main request and the first, second and third auxiliary requests correspond to the above-cited sets of claims, with the term "non-therapeutic" inserted before the word "method" at the beginning of claim 1. Even though it was held in point 2.4.1 of decision G 1/03 that an undisclosed disclaimer may be allowable to disclaim subject-matter excepted from patentability under Article 53(c) EPC, it was emphasised in the third paragraph of point 3 (and in point 2.4 of the order) of that decision that a claim containing a disclaimer must meet the requirement of clarity of Article 84 EPC.

In view of the fact that some of the claimed method steps do indeed constitute steps of treatment by therapy, as explained in points 2.1 and 2.2 above, the inserted term "non-therapeutic" contradicts the inherent therapeutic character of these steps. The present situation is analogous to those dealt with in point 5 of T 1635/09 and in point 2.1 of T 67/02, and similar to that underlying point 16 of T 1695/07, where such contradictory claims were held to be unclear. The claims of the amended versions of the main request and the first, second and third auxiliary requests therefore do not meet the requirement of clarity of Article 84 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated