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**Datasheet for the decision  
of 12 June 2013**

**Case Number:** T 1599/09 - 3.2.02

**Application Number:** 07003686.8

**Publication Number:** 1829572

**IPC:** A61M 5/142, A61M 5/168

**Language of the proceedings:** EN

**Title of invention:**

Method for using a pump set having secure loading features

**Applicant:**

Covidien AG

**Headword:**

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**Relevant legal provisions:**

EPC Art. 53(c), 111(1), 112(1)(a), 123(2)

**Keyword:**

"Exception to patentability - method for treatment by therapy (yes, main and first auxiliary requests - no; third auxiliary request)"

"Referral to the Enlarged Board of Appeal (no; second auxiliary request)"

"Added subject-matter (no; third auxiliary request)"

**Decisions cited:**

G 0003/98, G 0001/03, G 0001/04, G 0001/07, T 0245/87,  
T 0329/94, T 0238/06, T 1075/06

**Catchword:**

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Case Number: T 1599/09 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 12 June 2013

**Appellant:** Covidien AG  
(Applicant) Victor-von-Bruns-Strasse 19  
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**Representative:** Tomlinson, Edward James  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 17 February 2009  
refusing European patent application  
No. 07003686.8 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 17 February 2009 the Examining Division posted its decision to refuse European patent application No. 07003686.8 under Article 53(c) EPC.
- II. An appeal was lodged against this decision by the applicant by notice received on 8 April 2009, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 17 June 2009.
- III. By communication of 15 March 2013, the Board summoned the appellant to oral proceedings and forwarded its provisional opinion.
- IV. Oral proceedings were held on 12 June 2013.

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 13 May 2013, or in the alternative on the basis of one of the third auxiliary request, filed during the oral proceedings, and the fourth auxiliary request, filed with letter dated 13 May 2013. By letter dated 17 June 2009, the appellant also requested, as first auxiliary request, to order the Examining Division to continue the examination of the application on the basis of the main request and, as second auxiliary request, to have the following two questions referred to the Enlarged Board of Appeal:

"1. Does a claimed method for controlling the operation of medical equipment to be used for treating a patient

fall under the exclusion from patent protection pursuant to Article 53(c) EPC if the steps recited in the claim relate to the operation of the equipment itself and not to an interaction with a patient being treated?

2. If the answer to question 1 is in the affirmative: Is the method excluded from protection if as a consequence of the steps being performed, treatment of a patient may, but not necessarily, be affected in some manner not directly related to the claimed invention."

V. Claims 1, 10 and 12 of the main and the first auxiliary request read:

"1. A method of controlling the enabling of an enteral feeding pump for which a feeding set having an interlock device is adapted to be inserted into a recess of the enteral feeding pump, said method comprising:  
inserting the interlock device into the recess of the enteral feeding pump;  
emitting electromagnetic radiation in a direction for striking the inserted interlock device; and  
detecting at least a portion of the electromagnetic radiation striking the interlock device when the interlock device is properly inserted in the pump recess;  
such that operation of the enteral feeding pump to pump nutrient liquid in the feeding set in response to the detected electromagnetic radiation is enabled."

"10. The method as set forth in claim 1, wherein emitting electromagnetic radiation comprises operating

a first electromagnetic radiation source and wherein detecting the electromagnetic radiation striking the interlock device comprises operating a first electromagnetic radiation detector, and further comprising disabling operation of the enteral feeding pump in response to the first detector detecting electromagnetic radiation emitted by a source other than the first source."

"12. The method as set forth in claim 11, further comprising detecting electromagnetic radiation striking the interlock device during at least one of the emitter deactivations thereby indicating the interlock device is improperly inserted in the pump recess and disabling operation of the enteral feeding pump in response thereto."

Claims 2 to 9, 11, and 13 to 22 are further dependent claims.

Independent claim 1 of the third auxiliary request reads:

"1. A method of controlling the enabling of an enteral feeding pump for which a feeding set having an interlock device is adapted to be inserted into a recess of the enteral feeding pump, said method comprising:  
emitting electromagnetic radiation in a direction for striking an interlock device inserted into the recess of the enteral feeding pump; and  
detecting at least a portion of the electromagnetic radiation striking the interlock device when the

interlock device is properly inserted in the pump recess;  
such that operation of the enteral feeding pump to pump nutrient liquid in the feeding set in response to the detected electromagnetic radiation is enabled wherein the method does not include the step of controlling the operation of the enteral feeding pump to pump nutrient liquid."

Claims 2 to 20 are dependent claims.

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

Claim 1 of the main and first auxiliary request was directed not to a method of treatment of a human by therapy but to the control of the enabling of an enteral feeding pump. The invention provided a method for ensuring that the enteral pump could operate only when the interlock device was correctly positioned. If the interlock device was not correctly positioned, it was not possible to operate the pump. The claimed subject-matter was not directed to controlling the actual pumping action of the pump - it was directed to placing the pump in a state in which pumping may take place. The control of the pumping operation, wherein the amount of liquid pumped as a function of time was controlled, was not the subject-matter of the claim. Once the operation of the pump was enabled in accordance with the features of the claim, there was no direct consequence that the pumping action **did** take place only that it **may** take place, dependent on other features of the pump which were not claimed.

As such, the method of the invention had no direct effect on the treatment of a patient undergoing enteral feeding and the subject-matter of the claim was not excluded subject-matter. None of the steps recited in the method provided a functional link to the therapeutic treatment of a patient.

In G 1/07, 4.3.2, it was indicated that *"even if in such a case the use of the device itself requires the application of a surgical step to the body or is for therapeutic treatment the same does not apply to the claimed method for operating the device"*. Accordingly, operating a device which was for therapeutic treatment was not excluded from patentability. It was further stated that *"Methods which are merely directed to the operating of a device without themselves providing any functional interaction with the effects produced by the device on the body are teachings in which the performance of a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy is not required in order for the teaching of the claimed invention to be complete"*.

The enablement of the pump to pump nutrient as claimed did not include any functional interaction with the patient since it related only to a change in state of the pump from disabled to enabled. A separate change of state was required to change the pump from the state of non-pumping to the state of pumping but this was not a feature of the claim. This became evident from reference numeral 1418 in Figure 17, indicating that a flag was set for the execution of further software routines when it was detected that the safety interlock

device was correctly loaded. When this flag was set to ON or OFF, the pump was enabled or disabled, respectively.

The description of the invention (including the passages referred to in the impugned decision regarding Article 53(c) EPC) provided a comprehensive disclosure to the skilled person of how to construct and operate a pump set incorporating the claimed invention. The subject-matter for which protection was sought was however defined by the claims. These claims were restricted to a method for controlling the enabling of an enteral feeding pump and not a method for administering nutrient liquid to a patient.

Even if the claims were to be directed to a method of controlling an enteral feeding pump, the claimed subject-matter would not be excluded from protection under the provisions of Article 53(c) EPC. It was the established case law of the Boards of Appeal (T 245/87, T 329/94, T 238/06) that if a claimed method involved purely technical steps and did not include any interaction with the body, the provisions of Article 53(c) EPC did not apply. None of the features of the method recited in claim 1 related to an interaction with the body. A claim comprising method steps relating to the operation of a technical device which required no interaction with the patient for their implementation was not excluded from patent protection.

Moreover, the operation of the pump did not require the involvement of a medical doctor since it could be operated by the patient himself. Accordingly, the



claimed method did not result in a constraint to the freedom of the medical profession to apply the treatment of choice to their patients. As stated in the third paragraph of point 3.4.2.4 of G 1/07, the exclusion from patentability should not be applied to such methods.

Furthermore, enteral feeding did not provide a method of treatment by therapy as it did not relate to the treatment of a disease. Otherwise the term "therapy" would have to be considered to have a meaning going beyond the everyday meaning of the term, contrary to the arguments on interpretation of exceptions to patentability in accordance with the Vienna Convention contained in G 1/07 and the statements given in point 3.1 thereof.

As indicated in the 5th Edition of the book "Case Law of the Boards of Appeal", the policy behind the exclusion of methods of treatment by surgery or therapy *"was clearly to ensure that those who carry out such methods as part of the medical treatment ... should not be inhibited by patents"*. Nevertheless in point 6.1 of opinion G 1/04, it was stated that *"it follows that, for reasons of legal certainty, which is of paramount importance, the European patent grant procedure may not be rendered dependent on the involvement of such [medical or veterinary] practitioners"*. Rather, in connection with diagnostic methods, it was considered that if *"some or all of the method steps of a technical nature referred to under point 6.4.1 above are carried out by a device without implying any interaction with the human or animal body, for instance by using a specific software program, these steps may not be*

*considered to satisfy the criterion "practised on the human or animal body", because their performance does not necessitate the presence of the latter".*

Accordingly, only methods which had a direct interaction with the human or animal body were intended to be excluded from protection by the provisions of Article 53(c) EPC. Moreover, the meaning of the term "functional link" was not clear. Furthermore, the interpretation of decision G 1/07 given in T 1075/06 led to uncertainty as to how the provisions of Article 53(c) EPC were to be construed.

If there was any interaction with the patient in the present case, it was only "paper thin". According to G 1/07 the exception clause of Article 53(c) EPC was to be construed in a narrow manner and it could not have been intended to apply to the situation at issue since it would harm the development in the area of medical technology. Accordingly, should the present Board not grant the main and first auxiliary requests, there arose a point of law of fundamental importance as to the scope of exclusion from patentability of Article 53(c) EPC, such that the matter should be referred to the Enlarged Board of Appeal pursuant to Article 112 EPC.

The amendment of claim 1 of the third auxiliary request made it explicit that the claimed method did not include the actual pumping operation within the scope of protection. Accordingly, performing the method of claim 1 had no influence whatsoever on a patient desiring treatment. As indicated in G 1/03, a disclaimer may be allowable to disclaim subject-matter which, under Articles 52 to 57 EPC, is excluded from patentability for non-technical reasons.

## Reasons for the Decision

1. The appeal is admissible.
2. Main and first auxiliary requests - exception from patentability

Claim 1 of both these requests comprises the feature "operation of the enteral feeding pump to pump nutrient liquid in the feeding set in response to the detected electromagnetic radiation is enabled". Besides encompassing numerous embodiments where the pump is merely put in a state where it is permitted to operate (as stated, for instance, at page 12, lines 14 to 19, page 20, lines 8 to 10 and 30 to 32, page 22, lines 22 to 23, page 25, lines 27 to 29, page 26, lines 1 to 3, or page 27, lines 1 to 3), this feature also encompasses embodiments where the pump is actually operated. This becomes evident from the description of the sixth embodiment of Figure 11 in paragraph [00051] where it is stated (page 16, line 33 to page 17, line 1) that "the controller 77 will sense a "SET LOADED" condition **and initiate operation of the pump**" [emphasis added]. Further on, it is stated that "[d]uring operation of the pump, ... the safety interlock status is continuously monitored and if the status changes from "SET LOADED" TO "FAULT", the controller will **stop operating the pump**" [emphasis added]. Similarly, in the description of the fifth embodiment of Figure 9, described in paragraph [0048], it is stated (page 15, line 13 to 14) that the IR detector 239 "sends a signal to the controller to

**disable operation of the pump"** [emphasis added].

Disabling operation of the pump is also part of dependent claims 10 and 12. In the Board's view, this means that the pump, being in a state where it pumps fluid, is directly set into a state where it does not pump any more, i.e. it is switched off. It is not disclosed in this context that there are any intermediate steps between these two states. With regard to the output filtering 1418 referred to by the appellant, it is explicitly mentioned on page 22, lines 20 to 23, that such output filtering can be omitted. Accordingly, in view of dependent claims 10 and 12 and the cited passages of the description, claim 1 encompasses embodiments where the enteral feeding pump is actually operating to pump nutrient liquid.

From the beginning of paragraph [0035] it becomes clear that the feeding set 5 (comprising the safety interlock device mentioned in claim 1) comprises tubing providing a fluid pathway between a source of fluid and a patient, i.e. the nutrient liquid in the source of fluid and in the tubing is in direct connection to the patient. Accordingly, the operation of the pump results in nutrient liquid being pumped into the patient. It follows that there is a functional interaction with the patient, having a direct effect on his or her treatment. In this respect, the present situation is different from that considered in the decisions T 245/87, T 329/94 and T 238/06, referred to by the appellant.

Enteral feeding is used to provide nutrition to patients who cannot obtain nutrition by mouth or are unable to swallow safely. Such patients are suffering

from an incapacity or disease. Even though enteral feeding does not cure the underlying cause, it clearly alleviates and lessens the symptoms thereof. It further prevents malnourishment. According to the established case law of the EPO ("Case Law of the Boards of Appeal of the EPO", 6th edition 2010, I.B.4.4.1, first two paragraphs), the meaning of the term "therapy" is not restricted to curing a disease and removing its causes. It also includes in particular symptomatic and prophylactic therapy. Accordingly, enteral feeding is considered to fall under the meaning of the term "therapy". The question of whether or not the nutrition fluid also comprises medicine as mentioned at the beginning of paragraph [0002] dealing with the background of the invention can thus be left aside.

The appellant's argument that the patient can operate the enteral feeding pump himself, without a medical practitioner being involved, is not decisive with respect to the exception clause of Article 53(c) EPC. In point 6.3 of the Reasons of opinion G 1/04, it is clearly stated that *"whether or not a method is a diagnostic method within the meaning of Article 52(4) EPC [1973] should neither depend on the participation of a medical or veterinary practitioner, by being present or by bearing the responsibility, nor on the fact that all method steps can also, or only, be practised by medicinal or non-medicinal support staff, the patient himself or herself or an automated system"*. This finding is also applicable to therapeutic methods. It is noted that many forms of medicaments, e.g. in the form of tablets or pills, can be administered by the patient himself.

As stated at the beginning of point 4.1 of the Reasons of decision G 1/07, "*[i]t is established in the jurisprudence of the boards of appeal that a claim encompassing an embodiment which is excluded from patentability under now Article 53(c) EPC, then Article 52(4) EPC 1973, cannot be left unamended*". Since claim 1 of the main and the first auxiliary requests encompasses embodiments falling under the exception clause of Article 53(c) EPC as explained above, these requests cannot be allowed.

3. Second auxiliary request - referral of questions to the Enlarged Board of Appeal

The submission of a referral under Article 112(1) (a) EPC by a board of appeal presupposes that an answer to the question is necessary for the referring Board to be able to decide on the appeal (G 3/98, point 1 of the reasons). As detailed in point 2 above, in the present case there is an interaction between one of the claimed method steps and the patient being treated. The first question raised by the appellant (recited supra in point IV) is subject to the condition that the steps recited in the claim relate to the operation of the equipment itself and **not** to an interaction with a patient being treated. Accordingly, an answer to this question is not needed to decide the present case. This also applies to the second question which is only posed for the case that the answer to the first question is in the affirmative. A purely theoretical interest in clarifying points of law is not sufficient justification for a referral.

Under these circumstances it is not necessary to deal with the appellant's arguments that in the present case the interaction with the patient was only "paper thin", that according to G 1/07 the exception clause of Article 53(c) EPC was to be construed in a narrow manner and that it could not have been intended to apply the situation at issue since it would harm the development in the area of medical technology. The Board is also unable to recognise any uncertainty introduced by T 1075/06 to interpreting the provisions of Article 53(c) EPC. The Board is further of the opinion that the meaning of the term "functional link" indicated in point 4.3.2 of the reasons of G 1/07 and the case law cited in this passage is sufficiently established. Furthermore, it is explicitly stated in the last sentence of this passage that this is not an issue of law "*but a matter to be determined ... in the individual cases under consideration*".

Therefore, the appellant's second auxiliary request for referring the two questions recited in point IV to the Enlarged Board of Appeal under Article 112(1) (a) EPC is rejected.

4. Third auxiliary request

The clause "wherein the method does not include the step of controlling the operation of the enteral feeding pump to pump nutrient liquid" added at the end of claim 1 limits the subject-matter of the claim to the above-mentioned embodiments of the original disclosure in which the pump is merely set into a state where it is permitted to operate. This clause is therefore in accordance with Article 123(2) EPC.

The amendments inserted at pages 15 and 17 (clarifying that disabling or stopping of the pump is not part of the claimed invention) and the deletion of dependent claims 10 and 12 of the main request avoid inconsistencies or contradictions with claim 1.

Since embodiments in which the pump is actually operated, thus being in functional interaction with the patient, are no longer encompassed, the claimed subject-matter does not fall under the exception clause of Article 53(c) EPC.

Since the fulfilment of the further requirements of the EPC has not yet been examined, the Board finds it appropriate to remit the case to the Examining Division for the continuation of the examination procedure (Article 111(1) EPC).



**Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:

D. Hampe

E. Dufrasne