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Datasheet for the decision of 31 March 2009

Case Number: T 0635/07 - 3.2.02

Application Number: 99943785.8

Publication Number: 1109586

IPC: A61M 5/172

Language of the proceedings: EN

Title of invention:
External infusion device with remote programming, bolus estimator and/or vibration alarm capabilities

Patentee:
Medtronic MiniMed, Inc.

Opponent:
DISETRONIC MEDICAL SYSTEMS AG

Headword:
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Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 52(1), 54, 56

Keyword:
"Novelty (main request, yes)"
"Inventive step (main request, yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0635/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 31 March 2009

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 14 March 2007 revoking European patent No. 1109586 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: M. Noel
Members: S. Chowdhury
M. J. Vogel

Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division to revoke European patent No. 1 109 586.

II. The opposition was filed against the whole patent and based on Article 100(a) (lack of novelty and inventive step), Article 100(b), and Article 100(c) EPC 1973.

With its decision posted on 14 March 2007 the Opposition Division held that:

- The alleged case of public prior use was not proven to the hilt, mainly because it was not clear what had been prior used.
- The ground for opposition under Article 100(c) EPC prejudiced the maintenance of the patent in unamended form according to the main request.
- The subject-matter of claim 1 of the first auxiliary request lacked novelty.
- The subject-matter of claim 1 of the second, third, fifth and sixth auxiliary requests lacked an inventive step.
- The fourth auxiliary request was late-filed and not admissible.

The patent was revoked, accordingly.

III. A notice of appeal against this decision was filed by the patent proprietor on 11 April 2007 and the appeal fee was paid on the same day. The statement of grounds was submitted on 20 July 2007.

The following documents are of interest in the appeal procedure:

D1: EP-A-0 048 423
D2: DE-C-31 12916
D15: US-A-4 619 653
D16: US-A-5 376 070
H1: User manual dated 2/98 for an external insulin pump H-TRON®plus
H8: Insulinpumpenfibel, U. Thurm, 1996, pages 1-25.

IV. Oral proceedings were held on 31 March 2009. The following requests were submitted:

The appellant requested that the decision under appeal be set aside and a patent be maintained in amended form with claims 1 to 16 filed with the grounds of appeal (main request). Additional requests were to maintain the patent on the basis of one of the auxiliary requests I to III all filed with the grounds of appeal.

The respondent (opponent) requested that the appeal be dismissed.

V. Claim 1 of the main request reads as follows:

"An infusion device (10) adapted for external location, outside a body, and for infusion of a liquid from a reservoir (34) into a body, the infusion device comprising: a housing (20) adapted to contain a fluid reservoir (34); a drive mechanism (32), contained within the housing, operable to expel fluid from a fluid reservoir contained by the housing into the body; a processor (18) coupled to the housing and arranged to

control the infusion device; and a receiver (26) coupled to the housing and adapted to receive wireless and remotely generated commands, wherein the processor (18) is coupled to the housing and the receiver and is arranged to receive the wireless and remotely generated commands from the receiver (26) and to control the infusion device in accordance with the commands, and the infusion device further comprises an indication device (30, 28, 16) within the housing; characterized in that the indication device (30, 28, 16) is arranged to provide an audible indication or a vibration to indicate when a command has been received and indicate when the command is being utilised to control the infusion device such that the infusion device is capable of being concealed from view on an individual when being remotely commanded".

VI. The parties argued as follows:

Appellant

The claimed device was adapted for use on a location external of the body for infusing a liquid into the body. Infusion implied passing the liquid directly to body tissue, for example intravenously, subcutaneously, by a syringe, etc. Therefore, skin penetration means are implicit in the claimed device and such means are not a feature of an implanted infusion device, for example that of D2.

The feature F2 [see point 3.2 below] defined two functions, it required that an audible signal or vibration be emitted to indicate that a command was received and again when the command was being carried

out. No prior art document disclosed both the functions defined by the feature F2, in particular D2 did not disclose the second function.

The closest prior art document was D16, which failed to disclose the features D2 and F2 of Claim 1. The technical problem as defined in paragraph [4] of the patent in suit was to make it possible to enable reliable and safe operation of the pump while the pump was concealed from view. The solution to this problem must be sought in the field of external pumps since it arose only in this field and not in the case of implanted pumps which were inherently concealed during use. However, none of the documents dealing with external pumps either mentioned the stated problem nor hinted at a solution therefor.

Respondent

D2 disclosed all the features of claim 1, including F2. In its broadest interpretation "adapted for" meant "suitable for" and the D2 device was suitable for external use. Claim 1 of the patent in suit did not require skin penetration means, it was so broad that it also covered the case of a catheter feeding the liquid through the mouth. Moreover, the catheter of D2 was capable of penetrating the skin.

That feature F2 was disclosed in D2 was accepted by the opposition division and previously also by the appellant. It was largely a use feature and was disclosed on page 6, lines 57 to 63 of D2. Therefore, the combination of all the features of claim 1 was anticipated by D2.

The closest prior art was the pump described in documents H1 and H8, which had all the features of claim 1, including F2 but excepting E, E1, and the second part of D1. In particular, pages 4.4 and 4.5 of H1 described that 3 beeps were emitted to signal the receipt of a command to deliver a bolus amount of 3 units, and a long beep was emitted to signal that the flow had stopped, which was what feature F2 required.

H8, page 23, point 14 also disclosed discreet operation of the pump, as demonstrated at the oral proceedings by operation of the pump whilst inside a trouser pocket. Therefore, the objective problem was to enable the pump to be operated without having to fiddle under clothing, for example in the case of a skier or a woman with thin clothing.

The use of a remote control and a receiver to operate the pump would suggest itself immediately because these were commonplace in daily life, and also known in the art, as exemplified by D1, D15, etc. It would be common sense to alter the pump H1 as little as possible and transfer as few features as possible to the remote control device. Thus, the person skilled in the art would leave the signalling device on the pump housing and take only the command function to the remote control device. The use of the features E, E1 and D1 in the pump of H1 would be obvious, accordingly.

Reasons for the decision

1. The appeal is admissible.

Main request

2. Amendments

Claim 1 of the main request is an amended version of claim 1 as granted. The respondent had no objections to the amended claims and the Board sees no reason to disagree.

3. Preamble

3.1 The respondent had made an allegation of public prior use and cited documents H1 and H8, which described an external insulin pump called H-TRON®plus, in support of this allegation. In order to expedite the appeal procedure it is assumed for the present that prior use has been proven and that this pump is prior art. If, with this assumption, the prior use proves fatal to patentability then it would need to be proven subsequently. If not, the investigation as to prior use may be omitted.

3.2 The respondent's letter of 18 January 2008 gives a feature analysis of claim 1 on page 10, of which only the feature F2 is recited, it reads as follows:

"to indicate when a command has been received and indicate when the command is being utilised to control the infusion device such that the infusion device is

capable of being concealed from view on an individual when being remotely commanded".

3.3 Only the ground of opposition under Article 100(a) EPC was pressed in the appeal procedure.

4. Novelty

Novelty was discussed by the respondent only with respect to D2.

Claim 1 defines an infusion device adapted for external location, outside a body, for infusion of a liquid from a reservoir into a body. At the oral proceedings the appellant argued that "infusion" means the direct delivery of a liquid to body tissue through the skin, so that the above feature implies the presence of skin penetrating means, and that claim 1 is to be regarded as being limited in this respect.

The Board accepts that claim 1 is so limited, given the tenor of the patent in suit and the appellant's explicit statement that claim 1 is to be regarded as being limited in this respect. The claimed device is mainly for the infusion of insulin (which cannot be administered orally) and the like, directly to body tissue. The embodiment described with reference to the drawing includes a tubing set 38 for delivery of the liquid transcutaneously.

The skin penetrating means are essential to the claimed device, accordingly. D2 does not disclose such means. The respondent argued that the catheter shown in D2 would be capable of penetrating the skin, but this is

mere conjecture, there is no disclosure to that effect either explicitly or by some indication such as the catheter having a sharp (i.e. piercing) distal end.

By virtue of this feature alone the claimed subject-matter is novel over the device of D2.

5. Inventive step

5.1 The closest prior art

The field of external and implantable pumps are separate from historical, technical, and medical perspectives, in that different considerations play a role in these two types of devices. For example, there are different technical considerations involved in the properties of the housing (body compatibility), fluid leakage, and battery life. These are of vital concern in implanted devices but not particularly so in the case of external devices. Some problems are common to the two types of pumps, e.g. ensuring correct programming and operation of the device. However, the present technical problem relates to discretion during operation (see point 5.2, below), which problem arises in the case of external devices only because implanted devices are inherently concealed during use. For these reasons the closest prior art must be in the field of external pumps.

The respondent starts from H1/H8 as the closest prior art documents, accordingly. The Board concurs with the respondent in this respect.

5.2 However, the Board does not agree with the respondent regarding the technical problem to be solved in view of H1/H8. H8 states that the pump thereof should be operable without any trouble through clothing worn over it, and as demonstrated at the oral proceedings this aim is satisfactorily achieved. H8 does not indicate that such operation is inconvenient or that some improvement is necessary in this respect. It is quite possible that if the user were to be inconvenienced or embarrassed upon use of the device than he/she would seek out an isolated place, such as a toilet, to operate the device. The problem of discreet operation is not addressed by H1/H8.

In the absence of any indication that operation of the pump of H1/H8 might prove inconvenient or embarrassing to the user and that a problem is sought for this, no such problem may be derived from these documents, and the argument of the respondent that H1/H8 do address this problem, is an ex post facto consideration.

Instead, the problem set out in the patent in suit, in paragraph [4] must be taken as the present problem to be solved. This paragraph reads as follows:

"One drawback is the inability to conceal an external infusion pump and catheter tubing from view. Many users desire to hide the external pump under clothing so as not to seem different from normal people. However, this is inconvenient or impractical, especially for diseases such as diabetes, since a user must have ready access to the external pump for monitoring or administering extra amounts of medication (i.e., boluses during the course of the day). If a user has concealed the

external pump, the user must partially undress or carefully maneuver the external pump to a location that permits access to the display and keypad.".

The fact that this problem is not known in the prior art is itself an indication of inventive activity.

5.3 The solution proposed in the patent is to split up the pump into two parts, a remote control and a pump part. Moreover, consideration has to be given as to which features are to be removed to the remote control. According to the proposed solution the command part is to be in the remote control and the indication part in the pump unit. This ensures greater convenience of operation combined with safety and discretion.

There is no incentive to split the operation of the H1/H8 pump into two parts since, as shown above, there is no objective indication that there is a problem with the operation of this pump. However, even if this pump were to be split into two parts, then the indication part would be in the remote control as in commonplace remote controls, for example for TV sets, which would not correspond to the present solution.

5.4 Therefore, neither the problem set out in the patent nor its solution are known in the prior art, and claim 1 involves an inventive step, accordingly.

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 the first instance with the order to maintain the patent on the basis of the following documents:

   – Claims 1-16 filed as the main request with the grounds of appeal.
   – Description and Figures as granted.

The Registrar The Chairman

C. Moser M. Noel