Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [ ] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 17 January 2013

Case Number: T 1630/09 - 3.5.05

Application Number: 02786891.8

Publication Number: 1464023

IPC: G06F 19/00

Language of the proceedings: EN

Title of invention:
Medication delivery system

Applicant:
Baxter International Inc.

Headword:
Medication delivery system/BAXTER

Relevant legal provisions:
EPC Art. 52(1)

Relevant legal provisions (EPC 1973):
EPC Art. 56, 83, 84

Keyword:
"Sufficiency of disclosure (yes)"
"Clarity (yes - after amendment)"
"Inventive step (yes - after amendment)"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1630/09 - 3.5.05

D E C I S I O N
of the Technical Board of Appeal 3.5.05
of 17 January 2013

Appellant: (Applicant)
Baxter International Inc.
One Baxter Parkway
Deerfield, IL 60015 (US)

Representative:
Probert, Gareth David
Potter Clarkson LLP
The Belgrave Centre
Talbot Street
Nottingham NG1 5GG (GB)

Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 10 March 2009 refusing European patent application No. 02786891.8 pursuant to Article 97(2) EPC.

Composition of the Board:

Chair: A. Ritzka
Members: P. Corcoran
G. Weiss

Summary of Facts and Submissions

I. The present appeal is against the decision of the examining division to refuse the European patent application no. 02 786 891.8, publication no. EP 1 464 023. The decision was announced during oral proceedings on 18 February 2009 and the written reasons were dispatched on 10 March 2009.

II. The decision under appeal was based on a main request comprising claims 1 to 23 filed with the letter of 5 February 2009 and an auxiliary request comprising claims 1 to 24 filed with the letter of 16 January 2009.

III. According to said decision, the main request was not admitted into the proceedings pursuant to Rules 137(3) and 116(1) EPC on the grounds that it was late filed and not clearly allowable due to the introduction of amendments giving rise to new objections under Article 123(2) EPC.

The subject matter of claim 1 of the auxiliary request was found to lack an inventive step over the disclosure of the following document:

D1: WO 01/88828 A.

IV. Notice of appeal was received at the EPO on 22 April 2009 with the appropriate fee being paid on 23 April 2009. A statement setting out the grounds of appeal was received at the EPO on 17 June 2009. With the statement setting out the grounds of appeal, the appellant filed a new main request and five auxiliary requests.

V. In a communication accompanying a summons to oral proceedings to be held on 17 January 2013, the board gave its preliminary opinion that the appellant's requests were not allowable and, *inter alia*, made the following observations:

(i) With respect to the main request, the board expressed reservations as to whether the invention according to claim 1 of said request had been disclosed with sufficient clarity and completeness to comply with the requirements of Article 83 EPC 1973.

(ii) The board further expressed reservations as to whether claim 1 of the main request defined all of the essential technical features of the invention in a manner compliant with the requirements of Article 84 EPC 1973.

(iii) With respect to the question of inventive step, the board noted that the appellant had essentially argued to the effect that the invention according to the main request was distinguished over D1 in that it addressed the problem of incorrect medication delivery by verifying that the correct delivery channel of a multi-channel medication delivery device was activated. However, the alleged distinctions over the prior art appeared to rely on features in respect of which the board had reservations concerning compliance with the requirements of Articles 83 and 84 EPC 1973. The board was of the preliminary opinion that a meaningful discussion of the question of inventive step would require the question of compliance with

the requirements of Articles 83 and Article 84 EPC 1973 to be resolved in the appellant's favour.

VI. With a letter of reply dated 17 December 2012, the appellant filed a new set of requests comprising a main request and four auxiliary requests. A declaration from Mr James Martucci, one of the inventors designated in the present application, was also submitted.

VII. Oral proceedings were held as scheduled on 17 January 2013. During the oral proceedings the appellant submitted an amended main request to replace the main request on file. The appellant also submitted amendments to pages 3, 3A, 4, 5, 6 and 10 of the description.

VIII. Claim 1 of the main request submitted at oral proceedings reads as follows:

"A medication delivery system (20) for communicating and matching prescribed medication data from a first label (28) on a medication container (26) holding the medication (27) and patient data from a second label (29) on a tag (24) adapted to be worn by a patient, the first label also containing instruction on delivering the medication, and the medication data, medication delivery instruction, and patient data are provided in a machine readable format, the medication delivery system comprising:

(a) a medication delivery device (30) which is adapted to deliver the medication from the medication container to the patient said medication delivery device having a data port (38) for receiving information and multiple delivery channels (33); and

(b) a handheld computing device (22) having means (36) for reading the medication delivery instruction, the prescribed medication data and the patient data in the machine readable format and for comparing the prescribed medication data and the patient data to confirm a match between the data, the handheld computing device having a transmitter (32) for transmitting the medication delivery instruction from the handheld computing device to the medical device and wherein the medical device is adapted to deliver the medication to the patient according to the instruction,

wherein each delivery channel (33) of the medication delivery device has a third label (31) with the information to uniquely identify the channel in the machine readable format, the handheld computing device capable of communicating the information read in the machine readable format from the label (31) to the medication delivery device so that the appropriate channel is activated."

Claim 23 of the main request seeks protection for substantially the same subject-matter in the form of an independent method claim.

IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request submitted at oral proceedings, or the auxiliary requests 1 to 4, all auxiliary requests filed with the letter dated 17 December 2012.

X. Insofar as they are relevant to the present decision, the written and oral submissions made on behalf of the appellant during the present appeal proceedings, may be summarised as follows:

(i) Concerning the question of sufficiency of disclosure, it was submitted that the application complied with the requirements of Article 83 EPC 1973. In this regard, reference was made to the declaration from Mr James Martucci and the description which this declaration provided in respect of how the skilled person would have been able to put the invention into practice.

(ii) With respect to the main request, it was further submitted that, at the claimed priority date, programmable multi-channel infusion pumps were known *per se* and that the skilled person would have known how to communicate data read from a label on a pump channel to such a pump such that the pump channel identified by the data on the label was activated.

(iii) Concerning the question of inventive step, it was submitted that the claimed invention was clearly distinguished over the disclosure of D1. In particular, it was submitted that the handheld computing device of claim 1 comprised means for reading clinically relevant data (such as medication delivery instructions, prescribed medication data and patient data) in machine readable format and was further adapted to perform a verification check on the data which had been read and to subsequently transmit the medication delivery instruction to the medical device. The claimed invention further prevented incorrect medication delivery by verifying that the correct

delivery channel of a multi-channel medication delivery device was activated.

(iv) Although D1 disclosed embodiments which envisaged the use of a handheld computing device capable of transmitting data to a medical device, it was submitted that the disclosure of D1 in this respect was restricted to a handheld computing device whose functionality was limited to receiving and storing data from a stationary computer and transferring such data to a medical device.

(v) The disclosure of D1 did not include a handheld computing device which comprised means for reading and verifying clinically relevant data in machine readable format. Consequently, it was not capable of being used by a caregiver to capture and verify clinically relevant data and patient data prior to transferring a medication delivery instruction to a medical device.

(vi) Moreover, D1 did not contain any teaching aimed at preventing incorrect medication delivery by verifying that the correct delivery channel of a multi-channel medication delivery device was activated.

(vii) Although the skilled person could arguably have modified the system of D1 so as to arrive at the subject-matter of claim 1 of the main request, there was no discernible motivation for the skilled person to modify the teaching of D1 in the required manner. On this basis, it was submitted

that, starting from D1, the subject-matter of claim 1 of the main request could only be arrived at using hindsight.

XI. At the end of the oral proceedings the chair announced the board's decision.

Reasons for the Decision

1. The appeal is admissible. The board judges that the appeal is allowable for the reasons which follow.

Main request

2. *Article 83 EPC 1973*

2.1 Having regard to the appellant's submissions concerning the question of sufficiency of disclosure (cf. Facts and Submissions, item X(i) and X(ii) above), the following is noted.

2.2 Although the board has reservations as to whether the declaration from Mr James Martucci, one of the inventors, can be considered to reflect the knowledge of a person of average skill in the art, the passages of said declaration which are relevant to the subject-matter of claim 1 of the main request nevertheless provide information which, in the board's judgement, may be taken into account with respect to the question of sufficiency of disclosure.

2.3 According to item 4. of said declaration, the prototype system comprised a handheld computing device (a PALM

Handheld PDA device as disclosed on p.9 l.9-11 of the published application) whose operating software was programmed to scan a barcode attached to a pump channel, to log what pump channel had been scanned and to send a signal to the pump indicating the same. The pump was then programmed to activate or use the respective pump channel on the basis of the information received from the handheld computing device.

2.4 Referring to the appellant's submission to the effect that programmable multi-channel infusion pumps were known *per se* at the claimed priority date (cf. Facts and Submissions, item X(ii) above), the board considers this assertion to be supported by the reference in D1 to "modern infusion pumps that incorporate microprocessors and storage capability" (cf. D1: p.18 l.14-17). On this basis, the board is satisfied that the skilled person would have been capable of programming the handheld computing device to read data from a barcoded label on a pump channel and to communicate this data to the pump such that the pump channel identified by the data on the label was activated. In the given context, the board judges that the term "appropriate channel" as used in claim 1 of the main request is to be construed as denoting the pump channel identified by the data on the channel label read by the handheld computing device.

2.5 In view of the foregoing, the board concludes that the application discloses the invention according to claim 1 of the main request with sufficient clarity and completeness to comply with the requirements of Article 83 EPC 1973.

3. *Article 84 EPC 1973*

3.1 The board is also satisfied that, in view of the amendments to claim 1 of the main request, said claim now defines all of the essential technical features of the invention in a manner compliant with the requirements of Article 84 EPC 1973.

4. *Claim 1*

4.1 Claim 1 of the main request is directed towards a medication delivery system which comprises a medication delivery device and a handheld computing device.

4.2 According to claim 1, the handheld computing device has means for reading medication delivery instructions, prescribed medication data and patient data in a machine readable format and for comparing the prescribed medication data and the patient data to confirm a match between the data.

4.3 With respect to the medication delivery device, claim 1 specifies that this device has multiple delivery channels and that each delivery channel of the medication delivery device has a label with information to uniquely identify the channel in the machine readable format. Claim 1 further specifies that the handheld computing device is capable of communicating the information read in the machine readable format from the label to the medication delivery device so that the appropriate channel is activated.

5. *Inventive step*

5.1 D1, the only prior art document cited in the decision under appeal, represents the closest available prior art to the subject-matter of claim 1 of the main request.

5.2 D1 discloses a medication delivery system which comprises a medication delivery device such as an infusion pump ("patient specific asset", cf. D1: p.6 l.1-6) and a so-called "medical transaction carrier" (MTC) that contains information concerning past and present medical transactions (D1: p.5 l.6-8).

5.3 In some embodiments of D1, the MTC is an electronic message and no physical device need be used (D1: p.7 l.3-6; p.13 l.30-31). In other preferred embodiments of D1, the MTC is a handheld computing device such as a PDA (D1: p.5 l.26-30). In the latter embodiments, the handheld computing device is used for storing information and transporting the information from one location in a care-giving facility where medications are prepared for delivery to a patient's bedside.

5.4 There is, however, no teaching or disclosure in D1 to the effect that the handheld computing device is provided with means for reading data in a machine readable format and for performing a comparison to confirm a match between items of read data as recited in claim 1 of the main request.

5.5 Whereas D1 does disclose means for reading data in a machine readable format (e.g. a barcode reader), the disclosed means are attached to stationary computers

such as the nurse station computer system 60 or the bedside computer 70 of Fig. 1 (cf. D1: p.10 l.11-14; p.14 l.22-25) or to the medication delivery device ("patient specific asset", cf. claim 2 of D1).
There is no identifiable disclosure or suggestion in D1 to the effect that the handheld computing device should be provided with such means for reading data in machine readable format.

5.6 The disclosure of D1 concerning the MTC appears to be limited to downloading medical information from the hospital's information systems to the MTC (D1: p.19 l.3 - p.20 l.6) and exchanging data between the MTC and medication delivery devices or "patient specific assets" in the terminology of D1 (D1: p.20 l.19 - p.21 l.20). In the board's judgement, D1 neither discloses nor suggests that, in the embodiments where the MTC is realised in the form of a handheld computing device, this handheld computing device should be adapted to permit the capture of data in machine readable format and to perform verification checks on the read data as recited in claim 1 of the main request.

5.7 D1 also fails to disclose that the medication delivery device has multiple delivery channels each of which has a label in machine readable format and that the handheld computing device is used for communicating information read from such a label to the medication delivery device so that the appropriate channel is activated.

5.8 Compared to the system of D1, the system of claim 1 of the main request thus provides a handheld computing device which has additional data capture and

verification functionality and which further uses this additional functionality to enable the user of the handheld computing device to interact with a multi-channel medication delivery device so as to selectively activate a specific channel of said medication delivery device.

5.9 The modifications to the disclosure of D1 required to arrive at the subject-matter of claim 1 of the main request could arguably have been carried out by the skilled person without undue difficulty. However, the question of obviousness has to be decided by considering what the skilled person would have done, rather than what he hypothetically could have done.

5.10 In the board's judgement, the skilled person starting from D1 finds no teaching or suggestion in that document which would have led him to perform the specific modifications required to arrive at the subject-matter of claim 1 of the main request. Neither can the board identify any apparent reason why the skilled person would have been prompted to attempt these modifications on the basis of his common general knowledge. The board therefore concurs with the appellant's submissions to the effect that starting from D1 it would not be possible to arrive at the subject-matter of claim 1 of the main request without the use of hindsight (cf. Facts and Submissions, item X(vii) above).

6. *Conclusions*

6.1 In view of the foregoing, the board concludes that the subject-matter of claim 1 of the main request involves

an inventive step over D1. A similar finding applies to claim 23 of the request.

6.2 Having regard to its finding concerning the main request, it is not necessary for the board to consider the appellant's auxiliary requests.

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 with the order to grant a patent in the following version:
   - claims 1 to 23 submitted as main request at the oral proceedings;
   - description: pages 1, 2, 7, 8, 9, 11 to 18 as originally filed;
   - description: pages 3, 3A, 4, 5, 6 and 10 submitted as new pages at the oral proceedings;
   - figures 1 to 39 as originally filed.

The Registrar: The Chair:

K. Götz A. Ritzka