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Datasheet for the decision of 5 April 2017

Case Number: T 1457/12 - 3.2.02

Application Number: 01984973.6

Publication Number: 1355597

IPC: A61M5/142, G06F19/00

Language of the proceedings: EN

Title of invention:
PATIENT MEDICATION IV DELIVERY PUMP WITH WIRELESS COMMUNICATION TO A HOSPITAL INFORMATION MANAGEMENT SYSTEM

Patent Proprietor:
B. Braun Medical, Inc.

Opponents:
Fresenius Medical Care Deutschland GmbH
Fresenius Kabi Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 100(c), 123(2)

Keyword:
Added subject-matter (yes)

Decisions cited:

Catchword:

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Case Number: T 1457/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 5 April 2017

Appellant: (Patent Proprietor)	B. BRAUN MEDICAL, INC. Suite 150, 1601 Wallace Drive Carrollton, TX 75006 (US)
Representative:	Uexküll & Stolberg Partnerschaft von Patent- und Rechtsanwälten mbB Beselerstraße 4 22607 Hamburg (DE)
Respondent: (Opponent 1)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Schmelcher, Thilo RCD-Patent Postfach 3106 52118 Herzogenrath (DE)
Respondent: (Opponent 2)	Fresenius Kabi Deutschland GmbH Else-Krömer-Strasse 1 61352 Bad Homburg (DE)
Representative:	Maikowski & Ninnemann Patentanwälte Partnerschaft mbB Postfach 15 09 20 10671 Berlin (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 April 2012 revoking European patent No. 1355597 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	M. Stern
	P. L. P. Weber

Summary of Facts and Submissions

I. The patent proprietor lodged an appeal against the decision of the Opposition Division dispatched on 18 April 2012 revoking European patent No. 1 355 597.

II. The Opposition Division had revoked the patent because the ground for opposition pursuant to Article 100(c) EPC prejudiced the maintenance of the patent as granted.

III. Notice of appeal was filed on 18 June 2012 and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 17 August 2012.

IV. Oral proceedings were held on 5 April 2017.

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted.

The respondents (opponent 1 and opponent 2) requested that the appeal be dismissed.

V. Claim 1 of the granted patent reads as follows:

"1. An IV medication infusion pump (10) for use with a hospital information management system (HIMS) (60), the HIMS (60) including a receiver (61) which is connected to said HIMS (60), the receiver (61) capable of receiving at least one wireless signal (49), said IV pump comprising an infusion pumping mechanism, pump operation circuitry (43) connected to and coupled with the infusion pumping, mechanism of said IV pump (10); wherein the pump (10) and the HIMS (60) permit

monitoring pre-selected data about the pump; wherein a wireless signal transmitter (45) and receiver (61) are coupled in the pump (10) and in the HIMS (60) to allow monitoring of the pre-selected data about the pump; wherein the wireless signal transmitter (45) is connected to said pump operation circuitry (43) in said IV pump (10); characterized in that
(a) the pump operation circuitry (43) includes circuitry (41) for continuously monitoring pre-selected characteristics (15) of current infusion pumping operation (18);
(b) the wireless transmitter (45) is configured to permit continuous monitoring of current pump operating parameters by continuously transmitting, during pumping operation, at least one wireless signal (49) representing said preselected current pumping operation characteristics (15); and
(c) the receiver (61) is configured to permit continuous monitoring of current pump operating characteristics by continuously receiving said at least one wireless signal (49) from the IV pump (10) representing said current pumping operation characteristics (15), so that said HIMS (60) receives said current pumping operation characteristics (15) represented by said at least one wireless signal (49) from said IV pump (10)."

VI. The arguments of the appellant relevant for the present decision are summarised as follows:

On page 15, lines 20 to 25, the original application disclosed that while the pump was operating, the monitoring of pump operating characteristics was performed either continuously, periodically or at the change of a state of operation, as might be required. The expression "while the pump is operating" on

page 15, line 20 was a clear reference to the "current" pump operation. Hence, the monitored operating characteristics were to be interpreted as the current pump operating characteristics. In combination with original claim 1, it was thus disclosed to continuously transmit at least one signal representing the monitored current pump operating characteristics. Page 8, lines 3 to 16 disclosed that the pump monitoring circuitry 41 provided the current operating data to a wireless transmitter for wireless transmission to a hospital information management system (HIMS). Figure 6 schematically showed a circuit block identified by reference numeral 41 for the monitoring circuit, and the same block was also identified by reference numeral 45 for the wireless transmitter. Based upon the disclosure, read as a whole, it was clear to the skilled person that the pump circuitry functioned to continuously monitor and transmit current pump operating parameters to the HIMS receiver.

VII. The arguments of the respondents are mainly those on which the reasons for the present decision are based.

Reasons for the Decision

1. The appeal is admissible.

2. Article 100(c) EPC with Article 123(2) EPC

2.1 The original application (published as WO-A-02/36044) relates to an intravenous (IV) infusion pump used in a health care facility such as a hospital, provided with monitoring and record keeping of infusion pump operational characteristics, such as settings, parameters, conditions or states, through a hospital

information management system (HIMS) (page 1, lines 10 to 14).

2.2 Claim 1 of the granted patent defines an intravenous (IV) medication infusion pump (10) for use with a hospital information management system (HIMS 60), the pump comprising, in essence, a circuitry (41) for **continuously** monitoring pre-selected characteristics of current infusion pumping operation and a wireless signal transmitter (45) configured to permit continuous monitoring of current pump operating parameters by **continuously** transmitting a wireless signal representing said current pumping operating characteristics, the HIMS (60) including a receiver (61) for **continuously** receiving the transmitted signal.

2.3 It is undisputed by the parties that the application as filed discloses an IV infusion pump comprising a circuitry (41) for continuously monitoring pre-selected characteristics of infusion pumping operation and a wireless signal transmitter (45) for transmitting at least one wireless signal representing said current pumping operating characteristics, and an HIMS (60) including a receiver (61) for receiving the transmitted signal (original application, page 5, line 25 to page 6, line 4; page 15, lines 20 to 25; claim 1). That the monitoring of pre-selected characteristics of infusion pumping operation may be continuous is explicitly disclosed (if only once) on page 15, lines 20 to 25 as an alternative to, e.g., monitoring at regular intervals or upon the occurrence of an event that changes the state of the pump. The original application goes on to disclose, on page 15, lines 27 to 29, that the signals representing the pumping operating, or operation, characteristics are

transmitted by the wireless pump transmitter to the HIMS wireless signal receiver.

However, the original application does not explicitly disclose that this transmission and reception is performed **continuously**. This is not contested.

2.4 In the Board's view, the fact that the monitoring by the pump is continuous is not an implicit disclosure either that also the transmission of the monitored data needs to be continuous, as argued by the appellant.

The Board considers that it is technically perfectly feasible that the monitored data could first be stored in the pump during a period of time and then transmitted to the HIMS at periodic intervals or upon request by a supervising operator. The latter option is in fact explicitly mentioned in the original application on page 14, lines 7 to 10. There is hence no implicit disclosure either that the data transmission by the pump transmitter and its reception by the HIMS receiver should be continuous.

2.5 The appellant argued, moreover, that the expression "while the pump is operating" on page 15, line 20 was a clear reference to the "current" pump operation, and that page 8, lines 3 to 16 disclosed that the pump monitoring circuitry 41 provided the current operational data to a wireless transmitter 45 for wireless transmission to the HIMS. Such an embodiment was said to be shown in Figure 6, in which these reference numerals 41 and 45 were included in one and the same block labeled as "IV pump operations monitored and transmitted".

The aforementioned passage on page 8 discloses the monitoring circuitry 41 to provide such data as the entered data or the current operational data to a pump display 40 and to a wireless transmitter 45 for transmission to the HIMS. According to page 8, lines 6 to 11, the entered data or the current operational data which are provided to the pump display and to the wireless transmitter may include the nurse identification and/or number, a unique patient identification name and/or number, a drug name, a dosage, a rate, a running time, a total volume of infusion, or an alarm. Even if certain of the current operational data mentioned may be considered to be continuously monitored operational characteristics according to page 15, lines 20 to 25, the passage on page 8 does not disclose anything about how this data is displayed on the pump display and how it is transmitted to the HIMS. Moreover, even if some of the monitored data was assumed to be of such safety-relevant nature that the skilled person would recognise a compelling reason for understanding that its presentation on the pump display was real-time (for example, an alarm condition as disclosed on page 8, lines 11 to 13), it is open to speculation whether the transmission of this data to the the hospital information management system (HIMS) would need to be performed on a continuous basis as well.

2.6 The Board is therefore not convinced that a **continuous** transmission to and reception by the HIMS is implicitly disclosed in the application as filed.

2.7 For the aforementioned reasons, the Board considers that the subject-matter of claim 1 of the granted patent extends beyond the content of the application as filed. Hence, the ground for opposition under

Article 100(c) EPC in combination with Article 123(2) EPC prejudices the maintenance of the patent.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated