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Datasheet for the decision of 24 September 2014

Case Number: T 1064/11 - 3.2.02

Application Number: 03014696.3

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Title of invention:
Bottoming sensor

Applicant:
Stryker Corporation

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European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1064/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 September 2014

Appellant: (Applicant)	Stryker Corporation 2825 Airview Boulevard Kalamazoo, MI 49002 (US)
Representative:	Koepe, Gerd L. Koepe & Partner Patentanwälte Postfach 22 12 64 80502 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 23 November 2010 refusing European patent application No. 03014696.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	D. Ceccarelli
	P. L. P. Weber

Summary of Facts and Submissions

I. The applicant has appealed the Examining Division's decision, dispatched on 23 November 2010, to refuse European patent application No. 03 014 696.3.

II. In the impugned decision, the Examining Division mentioned the following documents:

D1: US-A-4,833,457;
D2: US-A-4,949,412.

It held that the subject-matter of claim 1 of the only then pending request was not novel over document D1.

III. The notice of appeal was received on 18 January 2011 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 28 March 2011.

IV. The Board summoned the appellant to oral proceedings and set out its provisional opinion in a communication dated 23 May 2014.

V. The oral proceedings took place on 24 September 2014.

VI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 11 of the request filed during the oral proceedings.

VII. Independent claim 1 of the appellant's request reads as follows:

"A cushioning device (10) comprising

- at least one inflatable therapeutic bladder (12) having a top surface (16) designed to have a patient positioned thereon that applies pressure to the at least one bladder (12), a bottom surface (18) and at least one side surface (20) positioned between the top and the bottom surfaces (16, 18);
- a bladder cavity (22) being defined by the top surface (16), the bottom surface (18) and the at least one side surface (20);
- (A) a first flexible conductive material (32) positioned away from the bottom surface (18) of the bladder (12), positioned within the bladder cavity (22) and capable of being attached to the top or side surface (16, 20) of the bladder (12) or an object (40) within the bladder cavity (22), and (B) a second flexible conductive material (34) positioned within the bladder cavity (22), positioned away from the bottom surface (18) of the bladder (12) and capable of being attached to the top or side surface (16, 20) of the bladder (12) or an object (40) within the bladder cavity (22), (C) the first conductive material (32) and the second conductive material (34) being separated from each other when no patient is on the cushioning device (10) and being separated when the cushioning device (10) does not exert too much pressure to the patient positioned on the cushioning device (10) so that the first and second conductive materials (32, 34) are capable of acting like a switch (30) for a reactive device (36);
- the reactive device (36) being electrically interconnected with the first and second conductive materials (32, 34), and when the first and second conductive materials (32, 34) contact

each other, the reactive device (36) is capable of responding by sounding an alarm and/or re-inflating the bladder cavity (22) with a fluid."

VIII. The appellant's arguments, as far as relevant for the present decision, are summarised as follows:

In view of the complete disclosure of the present application, in particular paragraph [0003] of the published version, the therapeutic bladder as claimed in claim 1 could be exclusively a bladder intended to be in direct contact with the patient.

Document D1 was the closest prior art for the subject-matter of claim 1 and disclosed a cushioning device comprising one therapeutic bladder, being the fluid-filled cushion shown in figures 7, 8 and 9, and a fluid manifold. The fluid-filled cushion did not carry the first and second conductive materials as defined in claim 1. In D1 upper and lower conductors 88 and 86, which corresponded to the first and second conductive materials of the invention, were positioned in the fluid manifold. The latter was not "a bladder on the top surface of which the patient is positioned" as defined in claim 1, since, in D1, the patient was positioned on the top surface of the fluid-filled cushion, i.e. above the fluid manifold, but not on its top surface. The fluid-filled cushion and the fluid manifold might be named "bladders". These bladders might be in a fluid-tight communication, interconnected via a fluid line. Nevertheless they were still two separate bladders. The decisive feature of the present invention was that the "switch" consisting of the conductive materials was within the cavity of the bladder supporting the patient and, contrary to D1, a

second separate bladder was not required. Document D1 also did not disclose flexible conductors attached to the top or side surface of the therapeutic bladder, "flexible" being a well-recognised and unambiguous term meaning that the conductors were made of an expandable material and were in the form of a sheet.

It followed that document D1 failed to disclose all the features of claim 1 defined after "(A)".

Following the problem-solution approach, the technical effect of the differentiating features of claim 1 was to achieve the aim of the invention as also explained in paragraphs [0009], [0018] and [0020] of the published application, i.e. preventing bottoming-out before it occurred. That was because, in use, in case of fluid leaking from the bladder, the action of the patient's weight on the upper surface of the bladder would bring the conductive materials continuously closer to each other. At the time the conductive materials came into contact with each other, the upper surface of the bladder was still away from the bottom surface, i.e. still not in a condition of bottoming-out. Hence, the invention reliably prevented excessive pressure being exerted to the patient positioned on the therapeutic bladder.

In view of that, the objective problem of the invention was to obtain an improved cushioning device reliably preventing the "bottoming" event with a simple structure and enabling the adjustment to the requirements of different patients.

In contrast to the invention, the device of document D1 could not prevent bottoming-out. As apparent from figure 9 and also described in column 7, lines 15

to 18, if there was a leak in the fluid-filled cushion, the upper and lower conductors positioned in the fluid manifold would only come into contact with each other at a time when the patient's skin or tissue was already experiencing an excessive pressure, i.e. not before the bottoming-out. This was due to the fact that the walls of the fluid manifold only collapsed when there was no fluid left in it. In that situation there was no fluid left in the fluid-filled cushion either, because, as also explained in column 9, lines 2 to 6, they could not have a different pressure.

Moreover, the structure of the cushioning device of document D1, comprising two bladders, was more complicated, difficult to adjust to the requirements of different patients and costly to maintain, as it required protection against leaks which might occur on a surface having an area of almost twice the size of that of the claimed invention.

Also, the provision of flexible conductors further contributed to inventive step.

Document D2 taught a particular circuit to detect when a therapeutic bladder had already bottomed out. For this reason it could not provide any hint to the skilled person to modify the cushioning device of document D1 and arrive at the subject-matter of claim 1.

It followed that the subject-matter of claim 1 was novel and inventive.

Reasons for the Decision

1. The appeal is admissible.

2. The invention as claimed in claim 1 relates to an inflatable cushioning device of the kind used to provide a suitable support for immobile patients confined to wheelchairs or beds.

The amount of pressure exerted on the skin of immobile patients over long periods of time by supporting cushions or mattresses has an important effect on their well-being. An excessive peak or average pressure on the skin can reduce blood circulation, thereby causing decubitus ulcers, also called bed sores or pressure sores, and other complications (paragraph [0003] of the published application).

The invention seeks to ensure that an optimal contact (or interface) pressure is maintained. In particular, it aims to avoid an unwanted excessive deflation or bottoming-out of the cushioning device, which would result in an unacceptably high contact pressure. This object is achieved by the means of a cushioning device of the so called self-monitoring type (paragraph [0006] of the published application) comprising a therapeutic bladder. The bladder lodges in its interior two conductive materials which act like an electric switch. Upon reaching an unacceptable level of deflation the two conductive materials come into contact with each other closing the switch circuit. In order to function optimally, both conductive materials are positioned away from the bottom surface of the bladder, such that the switch circuit is closed before bottoming-out of the bladder occurs. The closure of the circuit may

trigger an alarm or the re-inflation of the cushioning device.

3. It is not disputed that document D1, which also concerns a self-monitoring cushioning device of the type claimed in claim 1, is the closest prior art.

4. The embodiment of a cushioning device shown in figures 7 to 9 is the most relevant for assessing patentability of the subject-matter of claim 1 and is referred to below.

That cushioning device comprises an assembly with a fluid-filled cushion (48) and a fluid manifold (82). The fluid-filled cushion has a top surface designed to have a patient positioned thereon (column 1, lines 19 to 24). In use, the patient's weight is responsible for a certain pressure in the fluid-filled cushion and the fluid manifold. Although fluid-filled cushion 48 and fluid manifold 82 are indicated as being separate structural entities, it has to be remarked that there is fluid communication between them through fluid line 52 or through an internal fluid passage provided by fluid communication openings 34a and 50a, such that the fluid pressure in the fluid-filled cushion will always be equal to the fluid pressure in the fluid manifold (column 9, lines 2 to 6). The combination of fluid-filled cushion 48 and fluid manifold 82 therefore defines a single fluid space, which can be regarded as a single functional entity.

This functional entity comprises a bottom surface (bottom surface of fluid manifold 82 in figure 8) and side surfaces (the respective side surfaces of fluid-filled cushion 48 and fluid manifold 82).

The cushioning device further includes a first conductive material (conductive member 88, figure 8) positioned away from the bottom surface, positioned within the fluid manifold and capable of being attached to the top or side surface of the fluid manifold (the upper surface of fluid manifold 82, which is held in contact with the lower surface of fluid-filled cushion 48, both being attached to the respective lateral surfaces), in accordance with one of the options under "(A)" in claim 1.

The cushioning device further includes a second conductive material (conductive member 86, figure 8) positioned within the fluid manifold, positioned away from the bottom surface and capable of being attached to an object within the fluid manifold (regulating member 84, to which conductive member 86 is attached, is an object within the fluid manifold), in accordance with one of the options under "(B)" in claim 1.

The first conductive material and the second conductive material are separated from each other when no patient is on the cushioning device and when the cushioning device does not exert too much pressure to the patient positioned on the cushioning device so that the first and second conductive materials are capable of acting like a switch for a reactive device (column 9, lines 44 to 50), the reactive device being electrically interconnected with the first and second conductive materials, and when the first and second conductive materials come into contact with each other, the reactive device is capable of responding by sounding an alarm and/or re-inflating the bladder cavity (column 9, lines 50 to 55). The features under "(C)" as well as the features relating to the reactive device in claim 1

are therefore disclosed.

5. Following the appellant's arguments, the fluid-filled cushion and the fluid manifold of document D1 define two structurally distinct cavities. The fluid-filled cushion is to be considered the inflatable therapeutic bladder within the meaning of claim 1, since it is its top surface - not that of the fluid manifold - which is designed to have a patient positioned thereon. Its internal cavity is therefore the bladder cavity according to the definition of claim 1.

Since in the cushioning device of document D1 the conductive materials are not positioned within the fluid-filled cushion, but rather in the fluid manifold, they are not positioned in the bladder cavity according to the definition of claim 1.

Semantically, it could therefore be argued, as the appellant also did, that all the features defined after "(A)" in claim 1 were not disclosed in document D1. From a technical point of view, however, the difference between the subject-matter of claim 1 and the disclosure of document D1 boils down to the fact that in document D1 the cushioning device is comprised of two structurally distinct bladders in fluid communication through corresponding openings instead of a single bladder and that the conductive materials of document D1 are not explicitly described as being flexible.

6. As regards the effect provided by the differentiating features, it is observed in particular that document D1 discloses a fluid communication between the fluid-filled cushion and the fluid manifold and a constant overlap between the lower surface of the fluid-filled cushion

and the upper surface of the fluid manifold. The two-bladder system of document D1 is functionally equivalent to a system consisting of one bladder with the second conductive material attached to an object fixed to the bottom of the bladder, and the first conductive material attached to the lateral surface, at some height above the object. The subject-matter of claim 1 clearly encompasses this latter system, which is also shown in figure 3 of the published application.

In such systems, irrespective of whether they comprise two bladders in fluid communication, as in document D1, or a single structural bladder, in case of a leak from the therapeutic bladder the two conductive materials will come into contact with each other only when the patient's weight starts to be supported by the object. Such a situation is described in paragraph [0031] of the published application with reference to figure 7, and in column 9, lines 7 to 34 of document D1.

The object (regulating member 84) of the cushioning device of document D1 is disclosed as being compliant, e.g. a foam material (column 6, lines 56 to 59), comparable to "object 40, like foam" according to paragraph [0028] and figure 3 of the present application. In view thereof, it is of little relevance whether the initial contact of the two conductive materials, i.e. where there is not yet full compression of the foam material, can be called bottoming-out or not. Contrary to the appellant's arguments, the Board takes the view that both the system of document D1 and the corresponding system consisting of a single bladder as encompassed by the subject-matter of claim 1 prevent too much pressure being exerted on the patient in a similar way.

Nor does the adjustability to the patient's needs differ in substance, since it is in relation to the adjustability of the pressure conditions within the therapeutic bladder. Whether the system comprises a single structural bladder or two bladders in fluid communication has no impact on the adjustability of the pressure conditions.

Therefore the Board cannot see any difference in functioning between the device of document D1 and the device according to claim 1.

The appellant's argument that a two-bladder system was costly to maintain, as it required the protection against leaks which might occur on a surface having an area of almost twice the size of that of the claimed invention, is not convincing either. The fact that a larger area is involved cannot in itself mean that the risk of leaks is higher. The latter depends on many other factors, such as the internal structure of the bladders and the elements they contain.

Finally, concerning the definition in claim 1 that the conductive materials are "flexible", the behaviour of the cushioning device of document D1 as well as that according to claim 1 will depend not only on the flexibility of the conductive materials but, also more importantly on the undefined flexibility of the object to which the second conductive material is attached.

7. Hence, the Board cannot accept the problem formulated by the appellant as the objective technical problem. Rather, in view of the lack of additional technical effects of the device according to claim 1, the problem has to be reformulated in a less ambitious way.

More particularly, the Board comes to the conclusion that the differentiating features only solve the problem of providing a constructional alternative to the two-bladder system of document D1.

8. For the skilled person, having two spaces in fluid communication through an opening or more openings, or a larger opening such that the two spaces can be considered actually to merge into a single space, is a mere matter of design, since there is no difference in function.

As regards the term "flexible", one might argue that the conductive materials of the cushioning device of document D1 are depicted in the drawings as being rather thin and should therefore possess a certain degree of flexibility. However, the question of the exact meaning of the term "flexible" may be left aside because the stiffness or flexibility of the conductive materials is neither explicitly described nor decisive for the proper functioning of the cushioning device of document D1. Hence, providing more or less flexible conductive materials in the cushioning device of document D1 is also considered a mere matter of design.

It follows that the skilled person would modify the two-bladder system of document D1 and arrive at the subject-matter of claim 1 whenever circumstances made it desirable.

9. It is therefore concluded that the subject-matter of claim 1 is not inventive, in breach of Article 52(1) EPC in conjunction with Article 56 EPC.

10. Since, for this reason alone, the appellant's request cannot be granted, it is not necessary to examine compliance with other requirements of the EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated