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**Datasheet for the decision  
of 25 May 2016**

**Case Number:** T 0369/12 - 3.2.02

**Application Number:** 06849080.4

**Publication Number:** 1937143

**IPC:** A61B5/03

**Language of the proceedings:** EN

**Title of invention:**

TECHNIQUES FOR EVALUATING URINARY STRESS INCONTINENCE

**Applicant:**

Pneumoflex Systems, LLC

**Headword:**

**Relevant legal provisions:**

EPC Art. 56

**Keyword:**

Inventive step - main request (yes) - selection of closest  
prior art - ex post facto analysis

**Decisions cited:**

T 1939/12

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
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Case Number: T 0369/12 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 25 May 2016**

**Appellant:** Pneumoflex Systems, LLC  
(Applicant) P.O. Box 1658  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 17 October 2011  
refusing European patent application  
No. 06849080.4 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 17 October 2011, to refuse the application.
  
- II. The Examining Division did not allow the main request for the reason that the subject-matter of claim 1 lacked an inventive step over the combination of the following documents:
  - D1: "Diagnosis of female bladder outlet obstruction and relevance of the parameter area under the curve of detrusor pressure during voiding: preliminary results", Cormier L et al, The Journal of Urology, Vol. 167, 2083-2087, May 2002;
  - D3: US-A-2004/0181161.
  
- III. The notice of appeal was received on 31 October 2011. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 14 February 2012.
  
- IV. The Board summoned the appellant to oral proceedings and set out its provisional opinion in a communication dated 4 December 2015.
  
- V. With letters dated 25 January 2016 and 4 February 2016 the appellant filed amended application documents, following receipt of which the Board cancelled the oral proceedings.
  
- VI. The appellant's requests are that the decision under appeal be set aside and a patent be granted on the basis of the claims of the main request, filed with

letter dated 25 January 2016 or, in the alternative, of the auxiliary request filed with letter dated 14 February 2012.

VII. The following document, cited in the international search report, is also mentioned in the present decision:

D4: US-A-2002/0049425.

VIII. Claim 1 of the main request reads as follows (compared with claim 1 of the main request on which the impugned decision was based, additions have been underlined and deletions struck through by the Board):

"Apparatus for detecting urinary stress incontinence, comprising:

~~a. a nebulizer containing a composition of L-tartrate in a pharmaceutically acceptable carrier,~~

ba. a pressure sensing catheter (300) insertable into a patient's bladder; ~~and~~

eb. a processor (504) for receiving electrical signals from the pressure sensing catheter in which the processor is configured to repetitively sample the electrical signals and in which the processor is configured to record sample pressure levels and to display a plot of samples of the electrical signals and in which the processor is configured to calculate the area under a curve resulting from the plot of the samples of the electrical signals received during involuntary coughs, characterized in that

the apparatus further comprises:

c. a nebulizer containing a composition of L-tartrate in a pharmaceutically acceptable carrier, wherein activation of the nebuliser generates a signal which in turn initiates the step of recording pressure

levels detected by the pressure-sensing catheter (300)."

Claims 2 and 3 are dependent claims.

IX. The appellant's arguments may be summarised as follows:

The problem addressed by the invention was that of diagnosing urinary stress incontinence and distinguishing it from urinary incontinence that may be due to other causes. The fact that the pressure response in the bladder to an induced involuntary cough differed from that in response to a voluntary cough proved useful in assisting the diagnosis. With the apparatus according to the invention, a dose of L-tartrate could be administered to a patient by the means of a nebuliser, thereby inducing an involuntary cough. The catheter and the processor could then be used to record the pressure responses in the bladder caused by the induced cough and a voluntary cough and use the two responses to assist in the diagnosis.

D1 was directed to standard urological testing, emphasising the measurement of urethral resistance. It was not concerned with the difference in bladder pressure response between voluntary or induced coughs. It provided no motivation to the skilled person to look for any method for simulating a cough.

D3 was concerned with measuring a patient's laryngeal cough reflex function, using electrodes positioned close to muscles involved in the cough reflex itself. It did not relate to measuring the effect of a cough on any other part of the body.

The objection of the Examining Division in the impugned

decision was thus based on a combination of references that addressed quite different problems. Such a combination was not obvious for the skilled person.

Claim 1 of the main request had been put in two-part form based on the disclosure of D4, a brief description of which was included in the description.

### **Reasons for the Decision**

1. The appeal is admissible.

2. *The invention*

The invention as defined in claim 1 of the main request concerns an apparatus for detecting urinary stress incontinence.

Urinary stress incontinence is one of several types of urinary incontinence, and occurs when there is a sudden pressure on the lower abdominal musculature, for example caused by a cough, sneeze, laugh or lifting (sentence bridging pages 1 and 2 of the application as filed).

According to the application, a proper diagnosis of the specific type of urinary incontinence is important in order to target it with the appropriate treatment, which may be different depending on the type of incontinence (page 2, second paragraph).

Several known tests are employed to detect urinary stress incontinence, such as the "Valsava maneuver", having the patient jump up and down, or bend down, or generate one or more strong voluntary coughs (second full paragraph on page 3). All of these tests aim to

achieve an increase in the intra-abdominal pressure so as to put pressure on the bladder and then observe whether incontinence develops.

The claimed invention aims at providing a further, more efficient test, which will aid in diagnosing urinary stress incontinence. In particular, it is proposed to use "a reflexive cough test (RCT), which triggers an involuntary cough on the part of the patient" (page 4, second full paragraph). This is achieved by using an apparatus for detecting urinary stress incontinence as defined in claim 1 of the main request, comprising, in particular, a nebuliser containing a composition of L-tartrate in a pharmaceutically acceptable carrier, for the administration of L-tartrate, the latter inducing involuntary coughs. The pressure in the bladder can then be measured by a pressure sensing catheter insertable into the bladder. A processor may record the sample pressure levels and calculate the area under a curve resulting from the plot of the electrical signals received during the involuntary coughs.

### 3. *Patentability*

3.1 The subject-matter of claim 1 of the main request is based in particular on claims 2 and 12 to 17 as originally filed and does not differ in substance from that of the main request on which the impugned decision was based. It specifically concerns an apparatus for detecting urinary stress incontinence by recording and processing sample pressure levels developed in a patient's bladder during involuntary coughs.

3.2 D1, considered the closest prior art by the Examining Division in the impugned decision, focuses on the relevance of the area under the curve of detrusor



pressure, i.e. the result of the subtraction of the abdominal pressure from the pressure in the bladder, during voiding in diagnosing female bladder outlet obstruction (last sentence of the abstract). D1 is not concerned with the detection of urinary stress incontinence. It does not describe any measurements to be performed during voluntary or involuntary coughs and it does not disclose a nebuliser containing a composition of L-tartrate in a pharmaceutically acceptable carrier as defined in claim 1. For this reason at least, the subject-matter of claim 1 is novel over D1.

D3 relates to an apparatus and method for evaluating a patient's laryngeal cough reflex, the apparatus comprising a nebuliser containing a composition made with L-tartaric acid. It has nothing to do with urology and hence it does not disclose a pressure sensing catheter insertable into a patient's bladder as defined in claim 1. For this reason at least, the subject-matter of claim 1 is novel over D3.

D4, cited in the international search report, concerns a urinary incontinence diagnostic system comprising a pressure measurement system (12 in figure 4) with a sensing catheter insertable in a patient's bladder (paragraph [0064]) for measuring pressure pulses induced, for example, by having the patient cough (paragraphs [0022] and [0091], and a processor for receiving electrical signals from the sensing catheter (paragraph [0065]). D4 does not disclose a nebuliser containing a composition of L-tartrate in a pharmaceutically acceptable carrier as defined in claim 1. Hence, the subject-matter of claim 1 is novel over D4 too.

The other documents cited in the first instance proceedings, but not considered in the assessment of patentability in the impugned decision, are less relevant. None of them disclose an apparatus for detecting urinary stress incontinence comprising a nebuliser containing a composition of L-tartrate in a pharmaceutically acceptable carrier as defined in claim 1.

It follows that the subject-matter of claim 1 is novel within the meaning of Article 54(1) and (2) EPC.

- 3.3 It is the established jurisprudence of the boards of appeal that the assessment of inventive step is performed by applying the problem-solution approach, according to which the closest prior art has to be identified first. If it is concluded that, starting from the closest prior art, the claimed subject-matter is inventive, then it will be inventive with any other piece of prior art as starting point.

In their decisions, the boards have repeatedly pointed out the essential criteria for the selection of the closest prior art. In essence, a piece of prior art qualifies as the closest if it represents the most promising springboard towards the invention from the perspective of the person skilled in the art (e.g. T 1939/12). Such a piece of prior art will have to be directed to a purpose or effect which is the same or at least the closest to that of the claimed invention. This normally implies that the closest prior art should belong to the same or a closely related technical field. If the skilled person had to start from a piece of prior art not concerned at all with the technical field and the problem solved by the invention, then he could not develop it further in the direction of the

invention without the benefit of hindsight, and hence without being inventive.

From the documents cited, as explained in point 3.2 above, neither D1 nor D3 are concerned with diagnosing urinary incontinence. As a consequence, any problem related to the specific detection of urinary stress incontinence, as formulated by the Examining Division in the impugned decision, cannot be derived from either of these documents and, for the reasons just mentioned, D1 and D3 can hardly be considered the closest prior art.

Only D4 relates to diagnosing urinary incontinence, albeit by employing some tests mentioned as the state of the art in the application as filed (page 3, second full paragraph). Clearly, it is concerned with a technical field much closer to that of the invention. In the Board's opinion, for this reason, it is D4 that qualifies as the closest prior art. As a consequence, the reasoning of the Examining Division in the impugned decision based on D1 as the closest prior art is flawed.

As explained in point 3.2 above, D4 fails to disclose a nebuliser containing a composition of L-tartrate in a pharmaceutically acceptable carrier.

Such a nebuliser permits the use of the claimed apparatus to cause involuntary coughs, which are then evaluated in the diagnosis of urinary stress incontinence by considering the pressure in the bladder induced by such coughs.

According to the application as filed, in particular page 11, last paragraph, the result is that a better

diagnosis of urinary stress incontinence can be performed.

Starting from D4, the objective technical problem is therefore how to improve the reliability of the specific diagnosis of urinary stress incontinence. The problem formulated by the Examining Division in point 17 of the impugned decision, directly concerning the stimulation of an involuntary cough, cannot be accepted, as it already contains an element of the proposed solution: the presence of the composition of L-tartrate implies the stimulation of involuntary coughs.

No available document addresses or hints at the objective technical problem. From D4 it is not derivable that the tests envisaged by it for the detection of urinary incontinence (paragraphs [0022 and [0091] in particular) suffer from any deficiency. The only document disclosing a nebuliser containing a composition made with L-tartaric acid is D3. However, D3 does not relate to the problem formulated above, as it does not even relate to urology. For this reason, the skilled person wishing to improve the diagnosis of stress incontinence would not even consider this document, and in any case could only combine it with D4 by making abundant use of hindsight.

For these reasons alone, the Board concludes that the subject-matter of claim 1 of the main request is inventive within the meaning of Article 56 EPC.

4. The description has been adapted, in particular citing D4, on which the two-part form of claim 1 of the main request is based.

5. Since the Board considers the main request to be allowable, there is no reason to examine the auxiliary request.

## 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 on the basis of:
  - Claims 1 to 3 of the main request filed with letter of 25 January 2016;
  - Description pages 1 to 3, 4a and 8 filed with letter of 25 January 2016, page 4 filed with letter of 4 February 2016, pages 5 to 7 and 9 to 12 as published;
  - Drawing sheets 1/7 to 7/7 as published.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated