

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen
(D) No distribution

D E C I S I O N
of 9 August 2005

Case Number: T 1136/04 - 3.2.2

Application Number: 98936780.0

Publication Number: 1001821

IPC: -

Language of the proceedings: EN

Title of invention:

Automated delivery device and method for its operation

Applicant:

Pfizer Health AB

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 52(1), 54, 56, 122

Keyword:

"Inventive step (yes, after amendment)"

"Restitution in integrum (yes, exceptional circumstances)"

Decisions cited:

J 0002/86, J 0007/82, J 0027/88, J 0027/90, J 0014/89,

T 0469/93

Catchword:

-



Case Number: T 1136/04 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 9 August 2005

Appellant: Pfizer Health AB

Representative: Christine Vanhée-Brossollet
European Pharma Patent Department Pfizer
23-25 Avenue du Docteur Lannelongue
F-75668 Paris Cedex 14 (FR)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 10 February 2004
refusing European application No. 98936780.0
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
E. Dufrasne

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 10 February 2004 to refuse European patent application No. 98 936 780.0.

II. The grounds of refusal were that the subject-matter of claim 1 did not involve an inventive step, having regard to D2 (WO-A-93/12726), and claim 33 defined a method of treatment of the human or animal body by surgery and was excluded from patentability by Article 52(4) EPC, accordingly.

The Board has also considered the document D1 (DE-A-4 420 232).

III. Although the decision was dispatched to the applicant's authorised representative by registered letter with advice of delivery on 10 February 2004, the applicant first reacted to this by letter dated 9 September 2004 requesting re-establishment of rights. At the same time the appellant (applicant) lodged an application for re-establishment, an appeal against the decision, filed corresponding statements and paid the prescribed fees.

IV. The applicant submitted that a significant reorganisation took place within its company, the most significant of which were:

- in 2003, Pfizer Inc. merged with Pharmacia AB and acquired its patents portfolio, including the present application;

- the corresponding file, together with many others, was transferred to St Louis, USA, to be placed under the internal responsibility of Mr Bauer, US Registered Patent Agent and Senior Patent Agent of Pfizer Inc.;
- the Pharmacia AB Patent Department, in Stockholm, was closed on 19 December 2003;
- the representative authorised before the EPO for the present application, Mr Elwe, left Pharmacia AB in December 2003 and was no longer present to receive the registered letter dated 10 February 2004 at corresponding address in Stockholm;
- all other patent attorneys previously in charge of patents and patent applications of Pharmacia AB left the unit and were no longer employed by that company;
- the registered letter dated 10 February 2004 was never received in St Louis by Mr Bauer;
- foreign local agents were informed by Pfizer Inc. of the acquisition of patents and patent applications and of transfer of responsibility but, by unintentional omission, no change of representative was registered at the EPO at that time, in particular for the present application;
- in June 2004, as a result of a further re-organisation, the file corresponding to the present application was further transferred to the Paris facilities, together with many others, and the change of authorised representative to Mrs Vanhée-Brossollet duly recorded at the EPO on 5 August 2004;

- registration of transfer of European patents and patent applications, including the present one, was requested by the acquiring company by letter dated 3 June 2004.

The EPO established, from postal investigation, that the registered letter including the decision dated 10 February 2004 was received at the address of the representative authorised at that time, on 12 February 2004. The acknowledgment of receipt unfortunately got lost and the identity of the person who effectively received the registered letter cannot be established.

A second notification of the decision was dispatched by registered letter on 9 July 2004 and duly reached the representative of the applicant authorised at that time, Mrs Vanhée-Brossollet. The applicant considers the reception of this second notification as the removal of the cause of non-compliance with the time limit under Article 122(2) EPC.

Regarding the "all due care" requirement under Article 122(1) EPC, further to the above-mentioned exceptional circumstances, the applicant submitted the following details to support the occurrence of an isolated mistake in a normally satisfactory system:

- the transfer of the patent cases was handled under a formal procedure established within the acquiring company, termed "Case Transfer Guidelines";
- the person in charge of the transfer was a highly experienced and reliable manager, employed by the

company since 1985 and responsible for patent docketing operations within its general Patent Services since 1991;

- most of the concerned cases were handled by outside patent firms, which were duly informed and instructed as to the transfer, without any loss of rights;

- only the notification by the EPO of the decision dated 10 February 2004 was never received by the person responsible at that time.

- V. The appellant requests that the re-establishment be allowed, that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 14 filed during the oral proceedings, Figures 1 to 4D as published, and a description to be amended for consistency with the new claims.

The appellant suggested that the case be remitted to the first instance in order to give it time to make the extensive amendments required in the description.

- VI. Claim 1 reads as follows:

"An injection device (1) including a) a housing (2), b) a syringe-type container (3) for a fluid arranged in the housing, the container having an opening, c) a needle (4) connected in fluid communication with the opening, the needle (4) having a front end in flow respect distal from the container (3) and a rear end in flow respect proximal to the container, the front end and the rear end defining an axis there between and a forward direction and a rearward direction, and d) a

pump (5,6) arranged to deliver fluid in a direction from the container through the needle, a switch-type sensor (10, 11) being able to convert the sensor state into an electromagnetic signal, a processor (15), receiving the electromagnetic signal and delivering a control signal (16) to an operational component of the device, the operational component including a message device (18), arranged to issue a message to the user, or an electromechanical device (7), wherein the sensor (10, 11) is able to change state in response to a predetermined proximity of an object (12) to the sensor in the forward direction, a needle cover (8) arranged over the needle in an extended position of the cover and being displaceable along a path substantially axial in relation to the needle, the sensor (10, 11) being able to change state in response to the presence of the needle cover in a predetermined retracted position along said path."

Reasons for the Decision

1. *Re-establishment of rights*

Since the appeal was not filed within the prescribed time limit of two months after the date of notification of the appealed decision (Article 108 EPC), the appellant first applies for re-establishment of its right to file an appeal (Article 122 EPC).

1.1 Admissibility

In accordance with Article 122(2) EPC, an application for re-establishment of rights must be filed within two

months of the date of removal of the cause of non-compliance with the missed time limit.

Under the case law of the Boards of Appeal, the removal of the cause of compliance is a matter of fact which has to be determined in the individual circumstances of each case (J 7/82, OJ EPO 1982, 391 reasons 3 and 4; J 27/90, OJ EPO 1993, 422, reasons 2.4). It occurs on the date at which the person responsible for the application is made aware of the fact that a time limit has not been observed (J 27/88, unpublished, reasons 2.3; J 27/90, reasons 2.3).

It is further established by the case law of the Boards of Appeal that when a decision is duly notified, it is presumed, in the absence of circumstances to the contrary, to have removed the cause of non-compliance with the time limit (J 27/90, Reasons 2.4).

In the present case, the decision of 10 February 2004 was notified to the official representative at that time, Mr Elwe, and was received at his registered address on 12 February 2004.

However, it has been convincingly demonstrated by the applicant that, at the time of delivery of the registered letter, the present application, together with many others, was transferred to a new company, that the corresponding file had been sent to the acquiring company's Patent Department in St. Louis, under the internal responsibility of Mr Bauer, that the Pharmacia AB Patent Department in Stockholm was closed, that the still registered representative, Mr Elwe, as well as all other patent attorneys, had left

Pharmacia AB and, moreover, were no longer present at corresponding address and finally that Mr Bauer had never received the registered letter dated 10 February 2004 in St. Louis.

These are, in the opinion of the Board, specific circumstances which justify not considering the delivery of the registered letter including the decision, on 12 February 2004, as having effectively made the responsible person aware of the decision, and accordingly, removing the cause of non-compliance with the missed time limit.

A second notification of the decision was dispatched by registered letter on 9 July 2004 and duly reached the representative of the applicant authorised at that time, Mrs Vanhée-Brossollet. The reception of this letter is considered by the Board as the removal of the cause of non-compliance with the missed time limit.

Without even considering the date of reception of that second notification, it appears that the request for re-establishment, filed in the EPO on 9 September 2004, was necessarily within the two months time limit from reception of the notification sent on 9 July 2004.

Therefore, the request for re-establishment complies with the requirement of Article 122(2) EPC and is admissible.

1.2 Allowability

Article 122(1) EPC requires, for re-establishment to be allowed, that the time limit has been missed despite

all due care required by the circumstances having been taken.

The case law of the Boards of Appeal has established that due care is considered to have been taken if the applicant demonstrates that the non-compliance with the time limit results from exceptional circumstances or from an isolated mistake within a normally satisfactory system (J 2/86, OJ EPO 1987, 362, reasons 4). In particular, internal reorganisations, removals and transfers have been recognised in specific cases as exceptional circumstances (T 14/89, OJ EPO 1990, 432, reasons 6; T 469/93 of 9 June 1994, unpublished, reasons 1).

In the present case, the occurrence of exceptional circumstances is acknowledged, as set out above under the analysis of the admissibility of the application for re-establishment.

Further, it appears that the transfer of the patent files was conducted under an established formal procedure and handled under the control of a qualified and experienced responsible person.

Finally, the mistake remained isolated, measures having been taken by the acquiring company even before the removal of the cause of non-compliance, in particular, on one hand in order to register before the EPO the transfer of all concerned patents and patent applications, and on the other hand to allow reception of the second notification of the decision by the responsible person.

On the basis of these considerations, the Board recognises that all due care required by the circumstances had been taken by the applicant.

The Board, therefore, allows the re-establishment of rights to enable the applicant's appeal to be deemed to have been filed within the time limits under Article 108 EPC.

Therefore, the appeal is admissible.

2. *Amendments*

Claim 1 is based on claims 1, 19, 21, 32, and 33 as originally filed, and is directed to the particular embodiment described with reference to the Figures, and all its features are derivable there from. The dependent claims correspond to corresponding claims as originally filed. All the claims are properly supported by the original disclosure accordingly, and are allowable under Article 123(2) EPC.

3. *Novelty*

Claim 1 features an axially displaceable needle cover which extends between extended and retracted positions thereof and, in a predetermined retracted position thereof, is able to cause a switch-type sensor to change its state and issue a signal. Neither of documents D1 or D2 discloses an injection device with such a switch-type sensor actuated by a displaceable needle cover, so that the subject-matter of the claim is novel by virtue of these features, at least.

4. *Inventive step*

- 4.1 The application relates to an injection device (a medical syringe, in particular) in which correct positioning of the device with respect to an object (in particular a patient) is of importance in order to prevent misuse resulting from incorrect positioning of the device (page 3, lines 5 to 9).

Claim 1 defines *a syringe having a needle provided with a cover*, which cover is axially displaceable between an extended position of the cover and a retracted position thereof, whereby in a predetermined retracted position thereof a switch-type sensor is able to change state and issue a signal to a processor.

The objective technical problem solved by this arrangement is to ensure correct positioning of an injection device relative to an object, as the device is moved towards the object, before the device is enabled for use.

- 4.2 D1 relates to a syringe type device able to measure the electric conductivity of particular tissue around a needle tip for the purpose of finding a specific type of tissue whose location under the skin is unknown.
- 4.3 D2 relates to a syringe arrangement with an ultrasonic head used to control the penetration of a cannula into a body joint. An ultrasonic head gives a static picture of the joint to facilitate finding a suitable insertion location and the permissible depth of insertion, but does not give a signal representative of a distance between the target and a reference point of the device.

4.4 The technical problem of the application is not relevant in either of D1 or D2. Nor does either of these documents disclose a cover over a needle, which cover is axially displaceable between extended and retracted positions thereof, and in which retracted position a switch-type sensor is able to change state and issue a signal to a processor.

4.5 Accordingly, the features defined in claim 1 for solving the stated technical problem are not known or suggested in the prior art, and the subject-matter of claim 1 involves an inventive step.

5. *Further procedure*

The set of claims filed at the oral proceedings relates to an injection device having a syringe-type container, corresponding to the device described with reference to the Figures. By contrast, large parts of the description do not relate to such a device, and the description requires extensive revision in order to render it consistent with the claims allowed by the Board. This revision concerns the various statements of invention, the objects of the invention, as well as the numerous embodiments proposed in the description.

In order to perform a satisfactory revision, the appellant suggested that it be given time to carry this out and that the case be remitted to the first instance. The Board, in view of the very specific context, accepts this suggestion and remits the case to the first instance for the completion of this step of the procedure.

The Board would like to stress that it is incumbent on the appellant to undertake a thorough and proper amendment of the description as indicated above.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to grant a patent on the basis of:
 - claims 1 to 14 filed during the oral proceedings;
 - Figures 1 to 4D as published;
 - a description to be adapted to the claims.

The Registrar:

The Chairman:

V. Commare

T. K. H. Kriner