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## Datasheet for the decision of 6 November 2013

Case Number: T 2443/12 - 3.2.02

05705996.6 Application Number:

Publication Number: 1670362

IPC: A61B17/04, A61B17/34,

A61B17/072

Language of the proceedings: ΕN

Title of invention:

IMPLANTABLE DEVICE FASTENING SYSTEM AND METHODS OF USE

## Patent Proprietor:

ALLERGAN, INC.

## Opponent:

withdrawn

Headword:

## Relevant legal provisions:

EPC Art. 111(1), 114(1), 114(2), 123(2), 123(3) EPC R. 111(2)

#### Keyword:

Late submitted material - correct exercise of discretion (yes) Amendments - added subject-matter (yes) - main to twentyfirst auxiliary request Amendments - added subject-matter (no) - twentysecond auxiliary request Appeal decision - remittal to the department of first instance (yes)

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Catchword:



# Beschwerdekammern **Boards of Appeal** Chambres de recours

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

Case Number: T 2443/12 - 3.2.02

DECISION of Technical Board of Appeal 3.2.02 of 6 November 2013

ALLERGAN, INC. Appellant: 2525 Dupont Drive (Patent Proprietor) Irvine, CA 92612 (US)

Representative: HOFFMANN EITLE

Patent- und Rechtsanwälte

Arabellastrasse 4 81925 München (DE)

Respondent: withdrawn

(Opponent)

Representative:

Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 17 October 2012 revoking European patent No. 1670362 pursuant to

Article 101(3)(b) EPC.

## Composition of the Board:

Chairman: E. Dufrasne Members: D. Ceccarelli

P. L. P. Weber

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# Summary of Facts and Submissions

- I. The appellant (patent proprietor) lodged an appeal against the Opposition Division's decision, dispatched on 17 October 2012, to revoke European patent No. 1 670 362 B1. The mention of the grant of the patent in the European Patent Bulletin took place on 1 December 2010.
- II. The opposition had been filed on the grounds of added subject-matter, lack of novelty, lack of inventive step and insufficiency of disclosure.

In the impugned decision, which was taken during oral proceedings on 4 October 2012, the Opposition Division held that claim 1 of each of the requests presented by the proprietor contained subject-matter extending beyond the content of the patent application as originally filed. In reaching this conclusion, the Opposition Division took into account in particular the opponent's submissions on added subject-matter first presented with a letter dated 28 August 2012.

- III. The notice of appeal was received on 26 November 2012 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 18 February 2013.
- IV. The opponent withdrew the opposition on 11 December 2012.
- V. Oral proceedings before the Board took place on 6 November 2013.
- VI. The appellant's final request was that the decision under appeal be set aside and that the patent be

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maintained on the basis of the main request or, in the alternative, of one of the first to twentieth auxiliary requests, all filed with letter dated 18 February 2013, or one of the twenty-first and twenty-second auxiliary requests filed during oral proceedings.

- VII. The different versions of claim 1 are reported below.
  - a) Claim 1 of the main request reads as follows:

"A system for implanting an injection port, comprising:

- (a) an implantable injection port (10),
  comprising:
  - a housing (12);
  - a septum (11) retained by the housing, one end of the septum forming at least part of a top face of the implantable injection port, the septum being capable of penetration by a needle;
  - a space below the septum defining a fluid chamber;
  - an outlet conduit extending through the housing from the fluid chamber; and
  - a plurality of sharp fasteners (14, 114) attached to the implantable injection port, the fasteners (14, 114) enabling a user to attach the port to tissue, the fasteners (14, 114) each pivoting between an undeployed position and a deployed position, the deployed position extending below a bottom face of the injection port; and
- (b) a deployment tool (206) comprising a distal cover defining a recess that receives the injection port (10) therein, a proximal shaft

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extending upward from the distal cover to a proximal handle and manual actuator, and a transmission, wherein said transmission extends along the proximal shaft and transmits movement of the actuator through elements in the shaft to rotate an actuator lever in the distal cover that contacts and rotates the rotating disc and pivots the fasteners from their undeployed to their deployed positions,

characterized in that

the implantable injection port (10) further comprises a rotating disc (520) for simultaneously pivoting the fasteners (14, 114) from their undeployed to their deployed positions."

- b) Claim 1 of the first auxiliary request is identical to claim 1 of the main request.
- c) Claim 1 of the second auxiliary request reads as follows (additions with respect to claim 1 of the main request are underlined):
  - "A system for implanting an injection port, comprising:
  - (a) an implantable injection port (10), comprising:
    - a housing (12);
    - a septum (11) retained by the housing, one end of the septum forming at least part of a top face of the implantable injection port, the septum being capable of penetration by a needle;

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a space below the septum defining a fluid chamber;

an outlet conduit extending through the housing from the fluid chamber; and

a plurality of sharp fasteners (14, 114) attached to the implantable injection port, the fasteners (14, 114) enabling a user to attach the port to tissue, the fasteners (14, 114) each pivoting between an undeployed position and a deployed position, the deployed position extending below a bottom face of the injection port; and

(b) a deployment tool (206) comprising a distal cover defining a recess that receives the injection port (10) therein, a proximal shaft extending upward from the distal cover to a proximal handle and manual actuator, and a transmission, wherein said transmission extends along the proximal shaft and transmits a linear movement of the actuator through elements in the shaft into a rotational motion to rotate an actuator lever in the distal cover that contacts and rotates the rotating disc and pivots the fasteners from their undeployed to their deployed positions, wherein the actuator lever is snapped into the distal cover and rotationally mounts thereto about a vertical axis that coincides with a vertical axis of the injection port (10) when the port is received within the distal cover recess, and wherein the transmission includes a cable (617) attached to rotate the actuator lever,

## characterized in that

the implantable injection port (10) further comprises a rotating disc (520) for simultaneously

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pivoting the fasteners (14, 114) from their undeployed to their deployed positions."

- d) Claim 1 of the **third auxiliary request** is identical to claim 1 of the main request.
- e) Claim 1 of the **fourth auxiliary request** is identical to claim 1 of the second auxiliary request.
- f) Claim 1 of the fifth auxiliary request reads as follows (additions with respect to claim 1 of the main request are underlined):

"A system for implanting an injection port, comprising:

(a) an implantable injection port (10),
comprising:

a housing (12) <u>including a base plate</u> (510);

a septum (11) retained by the housing, one end of the septum forming at least part of a top face of the implantable injection port, the septum being capable of penetration by a needle;

a space below the septum defining a fluid chamber;

an outlet conduit extending through the housing from the fluid chamber; and

a plurality of sharp fasteners (14, 114) attached to the implantable injection port, the fasteners (14, 114) enabling a user to attach the port to tissue, the fasteners (14, 114) each pivoting between an undeployed position and a deployed position, the deployed

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position extending below a bottom face of the injection port; and

(b) a deployment tool (206) comprising a distal cover defining a recess that receives the injection port (10) therein, a proximal shaft extending upward from the distal cover to a proximal handle and manual actuator, and a transmission, wherein said transmission extends along the proximal shaft and transmits movement of the actuator through elements in the shaft to rotate an actuator lever in the distal cover that contacts and rotates the rotating disc and pivots the fasteners from their undeployed to their deployed positions,

characterized in that

the implantable injection port (10) further comprises a rotating disc (520) for simultaneously pivoting the fasteners (14, 114) from their undeployed to their deployed positions."

g) Claim 1 of the sixth auxiliary request reads as follows (additions with respect to claim 1 of the main request are underlined):

"A system for implanting an injection port, comprising:

(a) an implantable injection port (10),
comprising:

a housing (12) <u>including a plurality of</u> notches or openings (15);

a septum (11) retained by the housing, one end of the septum forming at least part of a top face of the implantable injection port,

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the septum being capable of penetration by a needle;

a space below the septum defining a fluid chamber;

an outlet conduit extending through the housing from the fluid chamber; and

a plurality of sharp fasteners (14, 114) attached to the implantable injection port and housed in the notches or openings (15) while allowed to move, the fasteners (14, 114) enabling a user to attach the port to tissue, the fasteners (14, 114) each pivoting between an undeployed position and a deployed position, the deployed position extending below a bottom face of the injection port; and

(b) a deployment tool (206) comprising a distal cover defining a recess that receives the injection port (10) therein, a proximal shaft extending upward from the distal cover to a proximal handle and manual actuator, and a transmission, wherein said transmission extends along the proximal shaft and transmits movement of the actuator through elements in the shaft to rotate an actuator lever in the distal cover that contacts and rotates the rotating disc and pivots the fasteners from their undeployed to their deployed positions,

#### characterized in that

the implantable injection port (10) further comprises a rotating disc (520) for simultaneously pivoting the fasteners (14, 114) from their undeployed to their deployed positions."

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h) Claim 1 of the seventh auxiliary request reads as follows (additions with respect to claim 1 of the main request are underlined):

"A system for implanting an injection port, comprising:

(a) an implantable injection port (10), comprising:

a housing (12) <u>including a plurality of</u>
notches or openings (15) and a base plate
(510);

a septum (11) retained by the housing, one end of the septum forming at least part of a top face of the implantable injection port, the septum being capable of penetration by a needle;

a space below the septum defining a fluid chamber;

an outlet conduit extending through the housing from the fluid chamber; and

a plurality of sharp fasteners (14, 114) attached to the implantable injection port and housed in the notches or openings (15) while allowed to move, the fasteners (14, 114) enabling a user to attach the port to tissue, the fasteners (14, 114) each pivoting between an undeployed position and a deployed position, the deployed position extending below a bottom face of the injection port; and

(b) a deployment tool (206) comprising a distal cover defining a recess that receives the injection port (10) therein, a proximal shaft extending upward from the distal cover to a proximal handle and manual actuator, and a transmission, wherein said transmission extends

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along the proximal shaft and transmits movement of the actuator through elements in the shaft to rotate an actuator lever in the distal cover that contacts and rotates the rotating disc and pivots the fasteners from their undeployed to their deployed positions,

characterized in that

the implantable injection port (10) further comprises a rotating disc (520) for simultaneously pivoting the fasteners (14, 114) from their undeployed to their deployed positions."

i) Claim 1 of the eighth auxiliary request reads as follows (additions with respect to claim 1 of the main request are underlined, deletions are struck through):

"A system for implanting an injection port, comprising:

(a) an implantable injection port (10), comprising:

a housing (12) <u>including a plurality of</u> notches or openings (15) and a base plate (510);

a septum (11) retained by the housing, one end of the septum forming at least part of a top face of the implantable injection port, the septum being capable of penetration by a needle;

a space below the septum defining a fluid chamber;

an outlet conduit extending through the housing from the fluid chamber; and

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a plurality of sharp fasteners (14, 114) attached to the implantable injection port via a rotating disc fastener system comprising a rotating disc (520), the fasteners (14, 114) housed in the notches or openings (15) while allowed to move, the fasteners (14, 114) enabling a user to attach the port to tissue, the fasteners (14, 114) each pivoting between an undeployed position and a deployed position, the deployed position extending below a bottom face of the injection port; and

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(b) a deployment tool (206) comprising a distal cover defining a recess that receives the injection port (10) therein, a proximal shaft extending upward from the distal cover to a proximal handle and manual actuator, and a transmission, wherein said transmission extends along the proximal shaft and transmits movement of the actuator through elements in the shaft to rotate an actuator lever in the distal cover that contacts and rotates the rotating disc and pivots the fasteners from their undeployed to their deployed positions,

#### characterized in that

the implantable injection port (10) further comprises a rotating disc (520) being for simultaneously pivoting the fasteners (14, 114) from their undeployed to their deployed positions."

j) Claim 1 of the ninth auxiliary request reads as follows (additions with respect to claim 1 of the main request are underlined): - 11 - T 2443/12

"A system for implanting an injection port, comprising:

- (a) an implantable injection port (10), comprising:
  - a housing (12) <u>including a base plate</u> (510);
  - a septum (11) retained by the housing, one end of the septum forming at least part of a top face of the implantable injection port, the septum being capable of penetration by a needle;
  - a space below the septum defining a fluid chamber;
  - an outlet conduit extending through the housing from the fluid chamber; and
  - a plurality of sharp fasteners (14, 114) attached to the implantable injection port, the fasteners (14, 114) enabling a user to attach the port to tissue, the fasteners (14, 114) each pivoting between an undeployed position and a deployed position, the deployed position extending below a bottom face of the injection port; and
- (b) a deployment tool (206) comprising a distal cover defining a recess that receives the injection port (10) therein, a proximal shaft extending upward from the distal cover to a proximal handle and manual actuator, and a transmission, wherein said transmission extends along the proximal shaft and transmits a linear movement of the actuator through elements in the shaft into a rotational motion to rotate an actuator lever in the distal cover that contacts and rotates the rotating disc and pivots the fasteners from their undeployed to their deployed

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positions, wherein the actuator lever is snapped into the distal cover and rotationally mounts thereto about a vertical axis that coincides with a vertical axis of the injection port (10) when the port is received within the distal cover recess, and wherein the transmission includes a cable (617) attached to rotate the actuator lever,

characterized in that

the implantable injection port (10) further comprises a rotating disc (520) for simultaneously pivoting the fasteners (14, 114) from their undeployed to their deployed positions."

k) Claim 1 of the tenth auxiliary request reads as follows (additions with respect to claim 1 of the main request are underlined):

"A system for implanting an injection port, comprising:

(a) an implantable injection port (10), comprising:

a housing (12) <u>including a plurality of</u> notches or openings (15);

a septum (11) retained by the housing, one end of the septum forming at least part of a top face of the implantable injection port, the septum being capable of penetration by a needle;

a space below the septum defining a fluid chamber;

an outlet conduit extending through the housing from the fluid chamber; and

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a plurality of sharp fasteners (14, 114) attached to the implantable injection port and housed in the notches or openings (15) while allowed to move, the fasteners (14, 114) enabling a user to attach the port to tissue, the fasteners (14, 114) each pivoting between an undeployed position and a deployed position, the deployed position extending below a bottom face of the injection port; and

(b) a deployment tool (206) comprising a distal cover defining a recess that receives the injection port (10) therein, a proximal shaft extending upward from the distal cover to a proximal handle and manual actuator, and a transmission, wherein said transmission extends along the proximal shaft and transmits a linear movement of the actuator through elements in the shaft into a rotational motion to rotate an actuator lever in the distal cover that contacts and rotates the rotating disc and pivots the fasteners from their undeployed to their deployed positions, wherein the actuator lever is snapped into the distal cover and rotationally mounts thereto about a vertical axis that coincides with a vertical axis of the injection port (10) when the port is received within the distal cover recess, and wherein the transmission includes a cable (617) attached to rotate the actuator lever,

## characterized in that

the implantable injection port (10) further comprises a rotating disc (520) for simultaneously pivoting the fasteners (14, 114) from their undeployed to their deployed positions."

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1) Claim 1 of the eleventh auxiliary request reads as
 follows (additions with respect to claim 1 of the
 main request are underlined):

"A system for implanting an injection port, comprising:

(a) an implantable injection port (10),
comprising:

a housing (12) <u>including a plurality of</u>
notches or openings (15) and a base plate
(510);

a septum (11) retained by the housing, one end of the septum forming at least part of a top face of the implantable injection port, the septum being capable of penetration by a needle;

a space below the septum defining a fluid chamber;

an outlet conduit extending through the housing from the fluid chamber; and

a plurality of sharp fasteners (14, 114) attached to the implantable injection port and housed in the notches or openings (15) while allowed to move, the fasteners (14, 114) enabling a user to attach the port to tissue, the fasteners (14, 114) each pivoting between an undeployed position and a deployed position, the deployed position extending below a bottom face of the injection port; and

(b) a deployment tool (206) comprising a distal cover defining a recess that receives the injection port (10) therein, a proximal shaft extending upward from the distal cover to a proximal handle and manual actuator, and a transmission, wherein said transmission extends

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along the proximal shaft and transmits <u>a linear</u> movement of the actuator through elements in the shaft <u>into a rotational motion</u> to rotate an actuator lever in the distal cover that contacts and rotates the rotating disc and pivots the fasteners from their undeployed to their deployed positions, wherein the actuator lever is snapped into the distal cover and rotationally mounts thereto about a vertical axis that coincides with a vertical axis of the injection port (10) when the port is received within the distal cover recess, and wherein the transmission includes a cable (617) attached to rotate the actuator lever,

characterized in that

the implantable injection port (10) further comprises a rotating disc (520) for simultaneously pivoting the fasteners (14, 114) from their undeployed to their deployed positions."

m) Claim 1 of the **twelfth auxiliary request** reads as follows (additions with respect to claim 1 of the main request are underlined, deletions are struck through):

"A system for implanting an injection port, comprising:

(a) an implantable injection port (10),
comprising:

a housing (12) <u>including a plurality of</u> notches or openings (15) and a base plate (510);

a septum (11) retained by the housing, one end of the septum forming at least part of a

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top face of the implantable injection port, the septum being capable of penetration by a needle:

a space below the septum defining a fluid chamber;

an outlet conduit extending through the housing from the fluid chamber; and

a plurality of sharp fasteners (14, 114) attached to the implantable injection port via a rotating disc fastener system comprising a rotating disc (520), the fasteners (14, 114) housed in the notches or openings (15) while allowed to move, the fasteners (14, 114) enabling a user to attach the port to tissue, the fasteners (14, 114) each pivoting between an undeployed position and a deployed position, the deployed position extending below a bottom face of the injection port; and

(b) a deployment tool (206) comprising a distal cover defining a recess that receives the injection port (10) therein, a proximal shaft extending upward from the distal cover to a proximal handle and manual actuator, and a transmission, wherein said transmission extends along the proximal shaft and transmits a linear movement of the actuator through elements in the shaft into a rotational motion to rotate an actuator lever in the distal cover that contacts and rotates the rotating disc and pivots the fasteners from their undeployed to their deployed positions, wherein the actuator lever is snapped into the distal cover and rotationally mounts thereto about a vertical axis that coincides with a vertical axis of the injection port (10) when the port is received within the distal cover

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recess, and wherein the transmission includes a cable (617) attached to rotate the actuator lever,

#### characterized in that

the implantable injection port (10) further comprises a rotating disc (520) being for simultaneously pivoting the fasteners (14, 114) from their undeployed to their deployed positions."

- n) Claim 1 of the **thirteenth auxiliary request** is identical to claim 1 of the fifth auxiliary request.
- o) Claim 1 of the **fourteenth auxiliary request** is identical to claim 1 of the sixth auxiliary request.
- p) Claim 1 of the fifteenth auxiliary request is identical to claim 1 of the seventh auxiliary request.
- q) Claim 1 of the sixteenth auxiliary request is identical to claim 1 of the eighth auxiliary request.
- r) Claim 1 of the **seventeenth auxiliary request** is identical to claim 1 of the ninth auxiliary request.
- s) Claim 1 of the **eighteenth auxiliary request** is identical to claim 1 of the tenth auxiliary request.

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- t) Claim 1 of the **nineteenth auxiliary request** is identical to claim 1 of the eleventh auxiliary request.
- u) Claim 1 of the **twentieth auxiliary request** is identical to claim 1 of the twelfth auxiliary request.
- v) Claim 1 of the twenty-first auxiliary request reads as follows (additions with respect to claim 1 of the main request are underlined, deletions are struck through):

"A system for implanting an injection port, comprising:

(a) an implantable injection port (10), comprising:

a housing (12) <u>including a plurality of</u> notches or openings (15) and a base plate (510);

a septum (11) retained by the housing, one end of the septum forming at least part of a top face of the implantable injection port, the septum being capable of penetration by a needle;

a space below the septum defining a fluid chamber;

an outlet conduit extending through the housing from the fluid chamber; and

a plurality of sharp fasteners (14, 114) attached to the implantable injection port via a rotating disc fastener system comprising a rotating disc (520), the fasteners (14, 114) housed in the notches or openings (15) while allowed to move, the fasteners (14, 114)

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enabling a user to attach the port to tissue, the fasteners (14, 114) each pivoting between an undeployed position and a deployed position, the deployed position extending below a bottom face of the injection port; and

(b) a deployment tool (206) comprising a distal cover defining a recess that receives the injection port (10) therein, a proximal shaft extending upward from the distal cover to a proximal handle and manual actuator, and a transmission, wherein said transmission extends along the proximal shaft and transmits movement of the actuator through elements in the shaft into a rotational motion to rotate an actuator lever in the distal cover that contacts and rotates the rotating disc and pivots the fasteners from their undeployed to their deployed positions, wherein the actuator lever is snapped into the distal cover and rotationally mounts thereto about a vertical axis that coincides with a vertical axis of the injection port (10) when the port is received within the distal cover recess, and wherein the transmission includes a cable (617) attached to rotate the actuator lever,

wherein the cable (617) is enclosed by a cable sheath (619) allowing a linear motion of the cable, the cable sheath being secured to the handle, and wherein the cable is attached to the actuator and the actuator lever, so that the linear motion of the cable is converted to the rotational motion to rotate the actuator lever,

wherein the actuator lever has curved lips (721) for gripping the baseplate,

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#### characterized in that

the implantable injection port (10) further comprises a rotating disc (520) being for simultaneously pivoting the fasteners (14, 114) from their undeployed to their deployed positions."

w) Claim 1 of the twenty-second auxiliary request reads as follows (additions with respect to claim 1 of the main request are underlined, deletions are struck through):

"A system for implanting an injection port, comprising:

(a) an implantable injection port (10),
comprising:

a housing (12) <u>including a plurality of</u>
notches or openings (15) and a base plate
(510), wherein said housing surrounds the
perimeter of the injection port;

a septum (11) retained by the housing, one end of the septum forming at least part of a top face of the implantable injection port, the septum being capable of penetration by a needle;

a space below the septum defining a fluid chamber;

an outlet conduit extending through the housing from the fluid chamber; and

a plurality of sharp fasteners (14, 114) attached to the implantable injection port <u>via</u> a rotating disc fastener system comprising a rotating disc (520), the fasteners (14, 114) housed in the notches or openings (15) while

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allowed to move, the fasteners (14, 114) enabling a user to attach the port to tissue, the fasteners (14, 114) each pivoting between an undeployed position and a deployed position, the deployed position extending below a bottom face of the injection port; and

(b) a deployment tool (206) comprising a distal cover defining a recess that receives the injection port (10) therein, a proximal shaft extending upward from the distal cover to a proximal handle and manual actuator, and a transmission, wherein said transmission extends along the proximal shaft and transmits movement of the actuator through elements in the shaft into a rotational motion to rotate an actuator lever in the distal cover that contacts and rotates the rotating disc and pivots the fasteners from their undeployed to their deployed positions, wherein the actuator lever is snapped into the distal cover and rotationally mounts thereto about a vertical axis that coincides with a vertical axis of the injection port (10) when the port is received within the distal cover recess, and wherein the transmission includes a cable (617) attached to rotate the actuator lever,

wherein the cable (617) is enclosed by a cable sheath (619) allowing a linear motion of the cable, the cable sheath being secured to the handle, and wherein the cable is attached to the actuator and the actuator lever, so that the linear motion of the cable is converted to the rotational motion to rotate the actuator lever,

wherein the actuator lever has curved lips (721) for gripping the baseplate,

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#### characterized in that

the implantable injection port (10) further comprises a rotating disc (520) being for simultaneously pivoting the fasteners (14, 114) from their undeployed to their deployed positions."

- VIII. The appellant's arguments are summarised as follows:
  - a) Late-filed submissions before the first instance

In the impugned decision, the Opposition Division had taken into account the opponent's submissions relating to added subject-matter, which had been filed after the expiry of the opposition period. Said submissions should be disregarded as latefiled. In deciding to admit these submissions, the Opposition Division had not properly exercised the discretion given to it by Article 114(2) EPC. In particular, the appellant's arguments had not been taken into account. More specifically, the Opposition Division had not explained to the appellant why it regarded the late-filed opponent's submissions as prima facie highly relevant, so that the appellant had had no opportunity to comment thereon.

The appellant had also not been given the necessary time to react to the new objections formulated in the late-filed submissions.

Section 5, last paragraph of the minutes of the oral proceedings before the Opposition Division indicated that the submissions had been admitted because they appeared highly relevant. However,

the minutes did not state anything about the requirement of prima-facie relevance. Also, the decision under appeal did not give any reason why the Opposition Division had considered the late-filed submissions to be prima facie highly relevant. Neither the opponent nor the Opposition Division had noticed the facts and evidence introduced with the late-filed submissions before 30 August 2012, i.e. almost one year after the end of the opposition period. This showed that there was no relevance at first sight, but at most after intense and repeated study of the case.

Hence, the Board should overrule the Opposition Division's decision on that point and disregard the late-filed submissions.

## b) Added subject-matter

General support for the system as defined in claim 1 of all requests was derivable from original claims 38 and 17 and from the description as originally filed, in particular page 1, penultimate paragraph, and page 9, second complete paragraph. The basis for the term "implantable injection port" was in particular page 1, first paragraph, in combination with page 10, second paragraph, and page 21, last paragraph.

Compared to claim 17 as originally filed, in claim 1 of the main request as well as of the first to twenty-first auxiliary requests it was not explicitly stated that the housing surrounded the perimeter of the injection port. This was however implicit from the remaining wording of the claims. In particular, a housing was always to be

understood as surrounding all the elements it housed. Since the housing was defined as being part of the implantable injection port, it would necessarily be at its periphery. Moreover, even if the claims could be interpreted as not requiring that the housing surrounded the periphery of the injection port, the definition of the position of the housing was not essential for the invention.

The subject-matter of claim 1 of the twenty-second auxiliary request was based on the embodiment of the deployment tool as described in connection with figures 63 to 70 and on the embodiment of the implantable injection port as described in connection with figures 58 to 62 and 73 to 77 as originally filed. Article 123(2) EPC did not require a "photogram" claim with each and every feature as depicted in said figures, but rather the essential structural and functional elements of said embodiments, all of which were present in the subject-matter of the claim. It followed that the claim did not comprise any non-allowable intermediate generalisation.

The subject-matter of claim 1 of the twenty-second auxiliary request also did not comprise features which were not disclosed in the above-mentioned embodiments.

In particular, the claim did not require a direct attachment of the plurality of sharp fasteners to the implantable injection port, but rather defined an indirect attachment "via a rotating disc fastener system", as it was the case in the embodiments concerned.

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The septum, the fluid chamber and the outlet conduit as defined found sufficient basis in figure 76 in conjunction with page 10, fourth paragraph of the application as filed, which described a septum of an injection port applicable to all embodiments.

The fact that the fasteners were defined as being "housed in the notches or openings" could not give rise to an interpretation according to which the fasteners should be completely enclosed by the notches or openings. The nature of notches and openings necessarily excluded a full enclosure. Moreover, the concept of housing the fasteners while providing for an exposure of them was originally disclosed on page 10, last paragraph. This applied also to the embodiments on which the subject-matter of the claim was based.

There was no reason to believe that the original application restricted the meaning of the term "transmission" to a gear system. Therefore the combination of the cable and the cable actuator as present in the above-mentioned embodiments and in the subject-matter of claim 1 of the twenty-second auxiliary request could indeed be defined as "transmission". This transmission comprised the cable and the cable sheath as elements in the shaft.

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## Reasons for the Decision

- 1. The appeal is admissible.
- 2. Admissibility of the opponent's submissions before the Opposition Division
- 2.1 As the appellant correctly remarks, the opponent's objections on added subject-matter first presented with letter dated 28 August 2012 were filed after the expiry of the nine-month period for giving notice of opposition as prescribed in Article 99 EPC.

Article 114(1) EPC prescribes that "In proceedings before it, the European Patent Office [...] shall not be restricted [...] to the facts, evidence and arguments provided by the parties and the relief sought."

Article 114(2) EPC prescribes that "The European Patent Office may disregard facts or evidence which are not submitted in due time by the parties concerned."

Even assuming that the opponent's objections were to be regarded as "facts or evidence" and not as mere "arguments", which was denied by the opponent in the proceedings before the first instance, the Board remarks that Article 114 EPC does not oblige the Opposition Division to disregard said objections but rather gives it the discretion to decide whether to take them into account or to decline to admit them as late-filed.

According to the established jurisprudence ("Case Law of the Boards of Appeal of the European Patent Office",

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7th edition 2013, IV.C.1.3.3), in exercising said discretion the Opposition Division should first examine the facts and evidence as to their relevance, and exceptionally admit them if, prima facie, there are reasons to suspect that they would prejudice the maintenance of the patent in suit. A board of appeal should only overrule the way in which a department of first instance has exercised its discretion if it concludes that said discretion has been exercised according to wrong principles, or in an unreasonable way.

2.2 As is apparent from the minutes of the oral proceedings before the first instance, the parties were given an opportunity to present comments on the issue of the admissibility of the allegedly late-filed submissions before the Opposition Division took the decision to admit them.

The appellant's argument that it was not given the necessary time to react to the objections formulated in said submissions is not convincing since, on the one hand, the submissions had been filed more than one month before the oral proceedings and, on the other hand, as confirmed by the appellant during the oral proceedings before the Board, no request for additional time was ever made by the appellant.

Although the Opposition Division did not explain to the parties the reasons for its decision during the debate, nor gave those reasons in the minutes of the oral proceedings, it cannot be asserted that the appellant was deprived of the right to be heard. The objections raised by the opponent were clearly apparent from its late submissions. Once the parties were given an opportunity to develop their lines of argumentation

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regarding the issue of admissibility - and, hence, prima-facie relevance of the objections - it was their own duty to address all the relevant points which might have influenced the decision. While Rule 111(2) EPC prescribes that "Decisions of the European Patent Office which are open to appeal shall be reasoned", there is no prescription that full reasons should be given before the written decision, in particular in the minutes of the oral proceedings, as long as the right to be heard is respected.

In the impugned decision (point 3.1) it is explained that the Opposition Division "considered the late filed arguments to be prima facie highly relevant to the validity of the disputed patent". Further on (points 4.6 to 4.9 and 5 to 5.2), an objection concerning a non-allowable intermediate generalisation, raised in the allegedly late-filed submissions, was found to compromise the maintenance of the patent. In the light of that, the Board cannot conclude that the Opposition Division did not reasonably examine the facts and evidence according to the appropriate criterion of prima-facie relevance.

The appellant's argument that objections could not be prima facie relevant if formulated almost one year after the end of the opposition period is also not convincing. Evidently, the Opposition Division could not assess the prima-facie relevance of an objection before knowing it. There may be several reasons why an objection was only identified late, but the Board does not see how they could concern its prima-facie relevance after its formulation.

2.3 Hence, the Board does not conclude that the Opposition Division exercised its discretion under Article 114 EPC

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according to wrong principles, or in an unreasonable way. As a result, the opponent's submissions filed with letter dated 28 August 2012 were correctly admitted into the proceedings.

# 3. Main request

Claim 1 of the main request corresponds to claim 1 of the patent as granted and is directed to a system for implanting an injection port, comprising an implantable injection port and a deployment tool.

General support for a deployment system for positioning an implantable device is provided on page 2, first paragraph of the original application. The Board agrees with the appellant that support for the implantable device in the form of an injection port is provided on page 1, first paragraph, stating the invention is in the field of implantable medical devices, in combination with page 10, second paragraph, explaining that an example of an implantable medical device could be an access port, and page 21, last paragraph, disclosing that the term "access port" and the term "injection port" are employed for the same concept in the patent application as filed.

The implantable injection port according to claim 1 comprises a housing and a plurality of sharp fasteners enabling a user to attach the port to tissue, the fasteners each pivoting between an undeployed position and a deployed position, the deployed position extending below a bottom face of the injection port.

These features are in particular based on claim 17 as well as figures 58 to 62 and 73 to 77 as originally filed, for example.

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However, claim 17 as filed and every original figure of a housing and a plurality of pivoting fasteners of an implantable injection port disclose a specific location of the housing with respect to the remaining elements of the injection port. In particular, said claim 17 recites that the housing surrounds the perimeter of the device to be attached to bodily tissue - i.e. the implantable injection port of claim 1 of the main request.

Claim 1 of the main request does not define such a location of the housing. The appellant's argument that such a location is implicitly present in the claim is not convincing. While the Board can follow the assertion that a housing should be construed as surrounding the elements it houses, it is to be remarked that claim 1 of the main request does not define the housing as including all the elements of the injection port. On the contrary, it is explicitly defined only that the housing, which is merely one of the elements of the injection port, retains the septum. It follows that, according to the appellant's argumentation, one can at most deduce that said housing has to surround the septum, but not the whole injection port.

Leaving out said definition of the location of the housing conveys the information that said housing could be located elsewhere with respect to other elements of the injection port. In particular, elements other than the fasteners could protrude from the housing. This information was however not originally disclosed.

Moreover, the Board sees a clear functional link between the originally disclosed location of the housing and the remaining elements of the injection

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port, in view of the aim of the invention. In particular, a housing containing all the elements of the injection port contributes to providing a smooth and self-contained device facilitating its implantation and extraction, as originally disclosed on page 9, second full paragraph.

It follows that the omission of the definition that the housing surrounds the perimeter of the injection port results in subject-matter extending beyond the content of the application as filed.

At least for this reason, the ground of opposition according to Article 100(c) EPC prejudices the maintenance of the patent according to the main request, i.e. as granted.

4. First to twenty-first auxiliary requests

Claim 1 of each of the first to twenty-first auxiliary requests also does not specify that the housing surrounds the perimeter of the injection port. In view of point 3 above, it follows that none of these requests can be allowed either, as they do not comply with Article 123(2) EPC.

- 5. Twenty-second auxiliary request
- 5.1 The Board shares the appellant's opinion that the subject-matter of claim 1 of the twenty-second auxiliary request is generally based on claims 17 and 38, on the embodiment of the deployment tool as described in connection with figures 63 to 70, and on the embodiment of the implantable injection port as described in connection with figures 58 to 62 and 73 to 77 as originally filed.

Compared to claim 1 of the main request, claim 1 of the twenty-second auxiliary request specifies that the housing surrounds the perimeter of the injection port and includes a plurality of notches or openings. As already explained in point 3 above, this feature finds a clear basis in claim 17 as originally filed.

The embodiment of the implantable injection port according to original figures 58 to 62 and 73 to 77 provides a disclosure for the base plate (510) of the housing, the plurality of sharp fasteners (501) and the rotating disk fastener system with the rotating disc (520) for pivoting the fasteners (original claim 38) and via which the fasteners are attached to the implantable injection port (page 19, second full paragraph) as claimed.

In view of the fact that fasteners 501 in figure 58 do not extend beyond their respective openings of the housing in the undeployed position and in view of the meaning given by the original application to the concept of housing the fasteners (page 10, fifth paragraph), the Board concludes that there is sufficient basis for the definition of "the fasteners housed in the notches or openings" as claimed.

The Board does not share the Opposition Division's view expressed in the impugned decision (point 4.10) that the expression "fasteners [...] attached to the implantable injection port" implies direct attachment and not via some other means. Neither does the usual meaning of the term "attached" exclude a further element for providing the attachment, nor does the original application hint at any special meaning of said term.

As the appellant also submits, figure 76 in conjunction with page 10, fourth paragraph of the application as filed discloses a septum of an injection port applicable to all embodiments and provides sufficient basis for the claimed septum, fluid chamber and outlet conduit.

The embodiment of the deployment tool according to original figures 63 to 70 and as described in the paragraph bridging pages 19 and 20 provides a disclosure for the distal cover (631) defining a recess that receives the injection port, the proximal shaft extending from the distal cover to the proximal handle (607) and the manual actuator (605), the transmission comprising the cable (617), the cable sheath (619) and the actuator lever (701) as claimed.

In particular, also in view of the fact that the original application does not define any specific meaning of the term "transmission", the Board does not see how the arrangement of cable 617 within its sheath 619, which extends along the proximal shaft and transmits a movement of manual actuator 605 to rotate actuator lever 701 for rotating the rotating disk should not be considered as "transmission" within the meaning of claim 1. Actuator lever 701 is snapped into distal cover 631 (page 20, second full sentence), rotates about a vertical axis that coincides with a vertical axis of the injection port when the port is received within the distal cover (figures 70 and 76) and has curved lips 721 for gripping the baseplate (page 20, third full sentence). Cable sheath 619 allows a linear motion of the cable (page 20, first full sentence), is secured to the handle and is attached to the actuator and the actuator lever (figure 63 and

page 20, second full sentence).

The Board is also satisfied that the structural and functional features defined in claim 1 of the twenty-second auxiliary request represent all necessary elements of the embodiment of the implantable injection port according to original figures 58 to 62 and 73 to 77, and of the deployment tool according to original figures 63 to 70, in view of their general functioning, necessary to obtain a suitable implantation and/or extraction of the implantable injection port as originally described on page 9, third paragraph.

Hence, claim 1 of the twenty-second auxiliary request complies with Article 123(2) EPC.

- 5.2 Compared to claim 1 of the patent as granted, claim 1 of the twenty-second auxiliary request adds further limiting features without omitting any features already present. It follows that claim 1 of the twenty-second auxiliary request also complies with Article 123(3) EPC.
- Since the opposition was filed on the grounds of added subject-matter, lack of novelty, lack of inventive step and insufficiency of disclosure, and the impugned decision only considered the ground of added subject-matter of claim 1, to preserve the right of a party to two instances and as also requested by the appellant during the oral proceedings, it is appropriate to remit the case to the department of first instance for further prosecution, in accordance with Article 111(1) EPC.

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# 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 for further prosecution.

The Registrar:

The Chairman:



D. Hampe E. Dufrasne

Decision electronically authenticated