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**Datasheet for the decision
of 13 December 2022**

Case Number: T 1381/18 - 3.2.08

Application Number: 12193316.2

Publication Number: 2561830

IPC: A61F2/95, A61F2/00, A61F2/24

Language of the proceedings: EN

Title of invention:
Two-part package for medical implant

Patent Proprietor:
Boston Scientific Scimed, Inc.

Former Opponent:
Edwards Lifesciences Corporation

Headword:

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:



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Case Number: T 1381/18 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 13 December 2022

Appellant: Boston Scientific Scimed, Inc.
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Representative: Peterreins Schley
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
5 April 2018 concerning maintenance of the
European Patent No. 2561830 in amended form.

Composition of the Board:

Chairwoman P. Acton
Members: A. Björklund
Y. Podbielski

Summary of Facts and Submissions

I. The patent proprietor (appellant) and former opponent filed appeals against the interlocutory decision of the opposition division finding that, on the basis of the auxiliary request 2 (then on file), the patent in suit (hereinafter "the patent") met the requirements of the EPC.

The opposition division decided that the subject-matter of the main request was not novel in view of

D4: US 4,011,947 B1

and that the subject-matter of auxiliary request 1a did not involve an inventive step starting from D4 in combination with

D5: US 2002/0120328 A1.

II. The former opponent withdrew their opposition with letter of 16 January 2019.

III. The appellant requested:

The decision to be set aside, rejection of the opposition and maintenance of the patent as granted.

The further requests are not relevant to the decision.

IV. Claim 1 of the main request (patent as granted) reads:

M1 "A medical implant and delivery tool package
(1) comprising:

M2 a wet compartment (3) containing a fluid;
M3 an implant (7) comprising a heart valve,
M4 wherein the implant is at least partially
stored inside the wet compartment (3);
characterized by
M5 a dry compartment (5); and
M6 a delivery tool (9) connected to the implant
at least partially stored inside the dry
compartment (5)."

V. The arguments of the appellant, where relevant to the decision, can be summarised as follows:

Novelty

D4 did not disclose a medical implant and delivery tool package having both a wet compartment and a dry compartment according to claim 1.

The term "wet compartment" required that the compartment is wet. In D4, the implant was stored inside a capsule which after removal of an outer packaging could be flushed with a solution in preparation of the implantation procedure. During storage, however, this capsule was dry.

The subject-matter of claim 1 was therefore novel over D4.

Inventive step

D4 taught that the capsule could be filled with an inert gas to assist in maintaining the valve free from dirt. It thus taught away from filling the capsule with a liquid solution for storage.

The skilled person would therefore not fill the capsule of the package of D4 with a liquid solution for storage even if they considered D5 which disclosed a package storing a heart valve in a liquid solution.

The subject-matter of claim 1 therefore involved an inventive step.

Reasons for the Decision

1. Novelty

The opposition division decided that the subject-matter of claim 1 is not novel in view of D4.

- 1.1 Figures 1 to 5 of D4 show a medical implant and delivery tool package. A heart valve 16 is stored inside capsule 40 and a tool 30 is connected to the valve. This assembly is stored inside a plastic bag 70 or bell-shaped protector 74. After removal of the bag 70 or bell-shaped protector 74, a solution can be injected into capsule 40 via entry port 50.
- 1.2 In the opposition division's view, capsule 40 could be seen as a wet compartment containing a fluid (an inert gas as described in column 6, lines 25 to 27), although during storage of the heart implant in the dry compartment, inside plastic bag 70, no liquid fluid or solution is inside the capsule. They pointed out that the storage in a liquid was not part of claim 1.
- 1.3 However, the skilled person understands the term "wet compartment" in the context of claim 1 as a compartment which is wet and not just suitable to be wet.

Feature M2 thus requires that a fluid making the compartment wet is inside the wet compartment during storage.

- 1.4 The package of D4 does not show a package simultaneously having a wet compartment and a dry compartment according to features M2 and M5.

At that point in time when the package of D4 has a dry compartment in the form of plastic bag 70 or bell-shaped protector 74 in which tool 30 is stored, capsule 40 does not contain a fluid making it a wet compartment.

When capsule 40 contains a solution and can be considered a wet compartment, plastic bag 70 or bell-shaped protector 74 have already been removed and can not be considered part of the package.

- 1.5 The subject-matter of claim 1 is thus novel over the package disclosed in D4 (Article 54(1) and (2) EPC).

2. Inventive step

The opposition division decided that the subject-matter of claim 1 of auxiliary request 1a did not involve an inventive step starting from D4 in view of D5. This line of argument applies also to the main request.

- 2.1 Starting from the package of D4 in its complete and closed state during storage, as shown in Figures 1 to 4, as the closest prior art the subject-matter of claim 1 of the main request differs from this package in the wet compartment defined in Feature M2.

According to the opposition division, this distinguishing feature solved the problem of preventing harmful substances from adhering to the heart valve.

- 2.2 As pointed out by the appellant, D4, column 6, lines 20 to 27, describes filling capsule 40 with an inert gas in order to assist in maintaining the valve free from dirt, i.e. harmful substances.

D4 thus already provides a solution to the problem posed.

The problem has hence to be reformulated in finding an alternative for preventing harmful substances from adhering to the heart valve.

Even if considering document D5, the skilled person would have no reason to fill capsule 40 with a liquid solution instead of an inert gas because this would make the injection of a solution containing an anticlotting compound, such as heparin, and antibiotics, such as penicillin, into the capsule and bathing of the valve therein, as described in column 5, lines 13 to 22 and column 6, lines 54 to 60 of D4, more difficult. The subject-matter of claim 1 is thus not obvious starting from the package of D4 in view of D5.

- 2.3 The subject-matter of claim 1 thus involves an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is maintained as granted.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated