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Datasheet for the decision of 6 February 2024

Case Number: T 0943/21 - 3.2.08

Application Number: 06749990.5

Publication Number: 1868532

IPC: A61F2/06, A61F2/958, B29K105/00, B29C33/38, B29L31/00, B29C49/20, B29C49/24, A61F2/95, B29C49/00

Language of the proceedings: EN

Title of invention:

METHOD OF STENT MOUNTING TO FORM A BALLOON CATHETER HAVING IMPROVED RETENTION OF A DRUG DELIVERY STENT

Patent Proprietor:

Abbott Cardiovascular Systems Inc.

Opponent:

Schulz Junghans
Patentanwälte PartGmbB

Relevant legal provisions:

RPBA 2020 Art. 12(6)
EPC Art. 83, 56

Keyword:
Late-filed objection - should have been submitted in first-instance proceedings (yes)
Sufficiency of disclosure - (yes)
Inventive step - (yes)

Decisions cited:
J 0014/19

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0943/21 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 6 February 2024

Appellant: (Opponent)	Schulz Junghans Patentanwälte PartGmbB Grossbeerenstraße 71 10963 Berlin (DE)
Respondent: (Patent Proprietor)	Abbott Cardiovascular Systems Inc. 3200 Lakeside Drive Santa Clara, CA 95054-2807 (US)
Representative:	Boult Wade Tennant LLP Salisbury Square House 8 Salisbury Square London EC4Y 8AP (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 29 April 2021 concerning maintenance of the European Patent No. 1868532 in amended form.**

Composition of the Board:

Chairman	C. Vetter
Members:	G. Buchmann
	F. Bostedt

Summary of Facts and Submissions

I. The opposition division decided that, account being taken of the amendments made during the opposition proceedings, the patent fulfilled the requirements of the EPC.

The opposition division found that the subject-matter of claims 1 and 21 according to the then valid auxiliary request 1 fulfilled the requirements of Articles 123(2) and 83 EPC and was novel and inventive (Articles 54(2) and 56 EPC).

II. The opponent filed an appeal against this decision.

III. Oral proceedings took place before the Board on 6 February 2024.

IV. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

V. The respondent (patent proprietor) requested that the appeal be dismissed and, therefore, that the patent be maintained in the text deemed allowable by the opposition division (main request), or as a subsidiary measure, that the patent be maintained on the basis of auxiliary requests 1 to 3 filed with the reply to the appeal.

VI. In the present decision, reference is made to the following documents:

D4 US 2003/0208254 A1
D5 US 6,666,880 B1

D6 US 2002/0110657 A1

VII. Main request

(a) **Claim 1** of the main request reads as follows. The numbering of the features has been added by the Board.

1.1
"A method of mounting a drug delivery stent (23) on a balloon catheter (20)
1.2
without damaging a drug delivery layer of the stent (23), the method comprising:
1.3
a) positioning a drug delivery stent (23) on a balloon (22) of a balloon catheter (20),
1.4
the stent (23) having a drug delivery layer;
1.5
b) positioning the balloon (22) with the drug delivery stent (23) thereon within a polished bore (12) of a mold (10)
1.6
formed at least in part of a metallic material; and
1.7
c) pressurizing and heating the balloon (22) within the mold (10) to mount the stent (23) on the balloon (22),
1.8
wherein the balloon (22) is heated by heating the mold (10) with a heat transfer medium which provides temperature control to the mold (10)
1.9
with a tolerance of about ±0.56 degrees C to about ±1.11 degrees C (about ±1 degree to about ±2

degrees F)."

(b) **Claim 21** of the **main request** reads as follows.

21.1
"An assembly for mounting a drug-delivery stent (23) on a balloon (22) of a balloon catheter (20)
21.2
without damaging a drug delivery layer of the stent (23), the assembly, comprising:
21.3
a) a mold (10)
21.4
having a body formed at least in part of a metallic material
21.5
and defining a polished bore (12)
21.6
configured to receive a balloon (22) of a balloon catheter (20) having a drug delivery stent (23) on the balloon (22),
21.6a
the mold (10) being a split-mold with hinged halves (11)
21.6b
and the bore (12) being defined by a polished inner surface having a polish finish equal to or smaller than about 0.4 microns; and
21.7
b) a heat transfer medium
21.8
which is configured to contact the mold (10) and thereby heat the mold (10) and the balloon (22) within the mold (10),
21.9
and which provides temperature control to the mold

(10)
21.10
with a tolerance of about ±0.56 degrees C to about ±1.11 degrees C (about ±1 degree to about ±2 degrees F)."

VIII. The arguments of the appellant can be summarised as follows:

Main Request - sufficiency of disclosure

The subject-matter of claim 1 was not disclosed sufficiently clear and complete for it to be carried out by a person skilled in the art.

Admittance of new argumentation

Further arguments raised under Article 83 should be admitted to the proceedings.

Main Request - inventive step

The subject-matter of claims 1 and 21 was not inventive in view of document D4 in combination with D6.

The subject-matter of claims 1 and 21 was not inventive in view of document D5 in combination with D6.

IX. The arguments of the respondent can be summarised as follows:

Main Request - sufficiency of disclosure

The subject-matter of claim 1 was disclosed sufficiently clear and complete for it to be carried

out by a person skilled in the art.

Admittance of new argumentation

The further arguments newly raised under Article 83 should not be admitted to the proceedings.

Main Request - inventive step

The subject-matter of claims 1 and 21 involved an inventive step.

Reasons for the Decision

1. *Sufficiency of disclosure - Article 83 EPC*

1.1 The appellant raised an objection under Article 83 EPC according to which the patent did not describe how the result of "mounting a drug delivery stent (23) on a balloon catheter (20) without damaging a drug delivery layer of the stent (23)" (Feature 1.2) could be achieved for step a) of the claimed method. Step a) included positioning of the stent on a balloon catheter. This involved crimping of the stent onto the balloon which could cause damage to the drug delivery layer due to the forces to be applied to the outer surface of the stent. Since nothing was said in the patent on how to avoid damage in step a), the skilled person was forced to perform experiments in order to find out how such damage could be avoided.

1.2 When assessing sufficiency of disclosure, it must be taken into account that the invention is carried out by a person skilled in the art. This person is aware of the common general knowledge in the technical field

concerned. This allows the skilled person to carry out parts of the invention which are well known in the art or which the skilled person can carry out without undue effort, without being provided by the patent with detailed information about such parts of the invention.

In addition, only if there are serious doubts, substantiated by verifiable facts, may a patent be objected to for lack of sufficient disclosure.

1.3 In the present case, step a) of the claimed invention is a well known procedural step in the preparation of balloon expandable stents for implantation because every balloon expandable stent has to be crimped and positioned on a balloon before implantation. This is done for drug delivery stents also, which were known before the application date of the patent in suit.

1.4 The appellant argued that the pressure forces and the impact onto the surface of the stent during step a) was comparable to the forces applied during step c) in which the balloon was pressurized and the balloon was heated within the mold to mount the stent on the balloon. This resulted in similar difficulties in avoiding damage to the drug delivery layer. The respondent, in turn, stressed that in step a) a pressure of 1 atm was sufficient for crimping the stent onto the balloon, which was considerably lower than the pressure needed in step c) which is, according to the patent, between 15-23 atm (paragraph [0023]). The appellant did not provide the Board with any evidence for its allegations. Therefore, the appellant's objection was not supported by verifiable facts which could have caused serious doubts that step a) can be carried out without damaging the drug delivery layer.

1.5 Therefore, the subject-matter of claim 1 of the main request is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

2. Admittance of new objections

2.1 Ill-defined parameter of "polish finish"

2.1.1 The appellant raised an objection under Article 83 EPC against the feature according to which the inner surface of the mold had a "polish finish". It was ill-defined and its meaning was not known to the person skilled in the art.

2.1.2 The appellant had not raised any objection against this feature during the opposition proceedings. However, it was already present in claim 24 as granted. If the appellant had been of the opinion that this feature could not be carried out by a skilled person, they could have raised the objection already in the notice of opposition. No reason has been brought forward by the appellant why the objection should not already have been raised in opposition. Additionally, no new situation has arisen in this respect in the course of the proceedings.

2.1.3 Therefore, this objection could and should have been raised already during the opposition proceedings.

2.1.4 The appellant argued that in the context of an objection under Article 83 EPC against the feature discussed above (point 1.1), they had already cited paragraph [0024] of the patent in the notice of opposition (page 7, point IV.). This paragraph mentioned the surface having a "polish finish".

Therefore, this aspect could be re-introduced into the appeal proceedings.

2.1.5 However, the objection raised in the notice of opposition aimed at a different feature of the claim, namely the question of how the result of "mounting a drug delivery stent (23) on a balloon catheter (20) without damaging a drug delivery layer of the stent(23)" could be achieved for step a) of the claimed method (see above). The present line of argumentation was not raised during the opposition proceedings.

2.1.6 The appellant referred to the decision J 14/19 according to which the use of an already discussed passage of a document in a different legal context represented an amendment of a party's case. From this, the appellant concluded that the use of an already discussed passage in the same legal context did not represent an amendment of the case. This reverse conclusion is, however, not possible.

2.1.7 Therefore, the objection is not admitted into the appeal proceedings according to Article 12(6), second sentence, RPBA 2020.

2.2 Temperature control

2.2.1 The appellant raised a further objection according to which the patent did not sufficiently disclose how the temperature tolerance values according to claim 1, Feature 1.9 could be achieved. This objection was also raised for the first time in the appeal proceedings.

2.2.2 However, Feature 1.9 according to which the heat transfer medium provides temperature control to the mold with a tolerance of about +-0.56°C was already

present in granted claim 21.

2.2.3 In the same way as discussed above, this objection could and should have been raised already during the opposition proceedings.

2.2.4 The mere fact that this feature was discussed in the decision of the opposition division in the context of inventive step, is no reason to admit an objection under Article 83 EPC against the same feature during the appeal proceedings.

2.2.5 Therefore, the objection is not admitted to the appeal proceedings according to Article 12(6), second sentence, RPBA 2020.

3. *Inventive step starting from D4 - Article 56 EPC*

3.1 Claim 1

3.1.1 Document D4 discloses

1.1

A method of mounting a stent on a balloon catheter, the method comprising:

1.3

a) positioning a stent on a balloon of a balloon catheter (paragraph [0009]),

1.5

b) positioning the balloon with the stent thereon (5) within a bore (4) of a mold (1) and

1.7

c) pressurizing and heating the balloon within the mold (1) to mount the stent on the balloon (paragraph [0032]),

1.8

wherein the balloon is heated by heating the mold (1)

with a heat transfer medium (e.g. hot blocks or hot oil, paragraph [0032]).

3.1.2 D4 does not disclose the use of a drug delivery stent and of a metallic mold having a polished bore.

According to the appellant, these distinguishing features solved the objective problems of providing a method for an alternative stent type, prevent roughening of the coating of the stent and provide improved precision of the mold. These problems were technically independent from each other, so that they could be treated separately when assessing inventive step. The solution as claimed was obvious when combining the method of D4 with the teaching of D6.

The problem of roughening the coating only arises, however, if a drug delivery stent is used in the method, which again is the solution of the first problem of providing an alternative stent. Therefore, these two objective problems are not independent from each other and cannot be treated separately.

3.1.3 D6 discloses a method for forming a balloon for a dilatation catheter, including the expansion of a balloon in a bore of a mold made from steel with a smooth mirror finish to provide a smooth finish on the balloon surface (paragraphs [0035]-[0036]).

Since neither D4 nor D6 discloses the use of a drug delivery stent, the skilled person is not given any incentive to use such a stent. Additionally, the temperatures used in the method of D4 (93-180°C) would damage a drug delivery layer. This teaches away from using the method of D4 for a coated stent.

Even when trying to use a drug delivery stent in the method of D4, and looking for a method to place it onto a balloon without damage, the skilled person cannot derive any teaching from D6 about how to solve this problem. D6 does not mention stents, let alone coated stents. The disclosure of the fact that a balloon will have a smooth finish by the polished inner surface of the mold, does not teach the skilled person that the drug delivery layer of a stent will not be damaged when using such a polished surface in a different method. Therefore, the allegation that the skilled person would use the mold having polished bore of D6 (paragraph [0036]) is only possible in hindsight.

The appellant also argued that according to D5, column 4, line 9ff it was known that the drug delivery coating must not be scratched. However, D5 uses a Teflon sheath for the coated stent. This does not teach the skilled person to use a polished metal mold.

3.1.4 Therefore, the subject-matter of claim 1 is inventive when starting from D4 in combination with D6.

3.2 Claim 21

3.2.1 Document D4 discloses

21.1

An assembly suitable for mounting a drug-delivery stent on a balloon of a balloon catheter (Figures 3-6), the assembly comprising:

21.3

a) a mold (Figure 3)

21.6

configured to receive a balloon of a balloon catheter having a stent on the balloon,

(21.6a)
the mold being a split-mold with halves (Figure 3);
21.7
b) a heat transfer medium (hot blocks, hot oil etc.; paragraph [0032])
21.8
which is configured to contact the mold and thereby heat the mold and the balloon within the mold,
21.9
and which provides temperature control to the mold (paragraph [0035]).

3.2.2 The subject-matter of claim 21 differs from this prior art at least in that the mold has a body formed at least in part from a metallic material and defines a polished bore with an inner surface having a polish finish equal to or smaller than about 0.4 microns. Additionally, the mold halves according to claim 21 are hinged to each other.

3.2.3 As discussed above in view of claim 1, D6 does not teach the skilled person to adapt the mold of D4 in order to make it suitable to mount a drug-delivery stent on a balloon without damaging a drug delivery layer of the stent.

Additionally, even when adapting the mold of D4 according to the teaching of D6, the skilled person would not arrive at an inner surface roughness of 0.4 microns, because D6 describes the bore to have a "mirror finish" with a surface roughness of 5-10 micrometers (paragraph [0036]). This is by a factor of 10 greater than the roughness defined in claim 1.

3.2.4 Therefore, the subject-matter of claim 1 involves an inventive step when starting from D4 in combination

with D6.

4. *Inventive step starting from D5 - Article 56 EPC*

4.1 Claim 1

4.1.1 Document D5 discloses

1.1
A method of mounting a drug delivery stent (10) on a balloon catheter (25)

1.2
without damaging a drug delivery layer of the stent (column 4, lines 9-12), the method comprising:

1.3
a) positioning a drug delivery stent (10) on a balloon (20) of a balloon catheter (column 5, lines 15-20),

1.4
the stent (10) having a drug delivery layer (column 4, lines 4-12);

(1.5)
b) positioning the balloon with the drug delivery stent thereon within a mold (30) formed from a Teflon sheath, and

1.7
c) pressurizing and heating the balloon within the mold (10) to mount the stent on the balloon (column 5, lines 26-34),

1.8
wherein the end of the balloon is heated by heating the mold (30) with a heat transfer medium (hot air, column 6, lines 16-21).

4.1.2 The subject-matter of claim 1 differs from the disclosure of D5 in that the mold is formed at least in part from a metallic material and has a polished bore, and in that the heat transfer medium provides

temperature control to the mold (10) with a tolerance of about ±0.56 °C to about ±1.11 °C (about ±1 °F to about ±2 °F).

4.1.3 The appellant argued that the problem to be solved was the provision of an alternative mold material. The skilled person would replace the Teflon mold (sheath 30) of D5 with the steel mold of D6.

However, in D5, only one end of the mold is heated while the remaining part of the mold is cooled. The two portions are separated by an insulating disc (50). Since the aim of D5 is to have different temperatures at different regions of the balloon (and the mold), the skilled person would not use a metallic mold as shown in D6 because metal conducts heat much better than Teflon. This would deteriorate the desired temperature difference between the portions of the balloon.

Therefore, it is not obvious to replace the mold (sheath 30) of D5 with the mold of D6.

The appellant argued that the desired temperature gradient could also be achieved with a metal mold. For that, the cooling had just to be intensified. This would, however, be a further modification of the method of D5 which is not obvious.

Furthermore, neither D5 nor D6 discloses a temperature control with a tolerance as claimed. The temperature at the heating nozzle 60 is said to be in a range between 82°C and 94°C, which corresponds to a tolerance of 12°C (column 6, lines 19-21). The appellant mentioned that D5 disclosed a temperature differential of approximately 30°C (column 6, lines 32-35). This is also no indication of the accuracy of the temperature

value itself.

4.1.4 Therefore, the subject-matter of claim 1 is inventive when starting from D5 in combination with D6.

4.2 Claim 21

4.2.1 Document D5 discloses

21.1
An assembly for mounting a drug-delivery stent (10) on a balloon (20) of a balloon catheter (25)
21.2
without damaging a drug delivery layer of the stent (10), the assembly, comprising:
21.3
a) a mold (30)
(21.4)
having a body formed of Teflon
21.6
configured to receive a balloon (20) of a balloon catheter (25) having a drug delivery stent (10) on the balloon (20), and
21.7
b) a heat transfer medium (hot air from heat nozzle 60)
21.8
which is configured to contact the mold (30) and thereby heat the mold (30) and the balloon (10) within the mold (30),
21.9
and which provides temperature control to the mold (10).

4.2.2 In the same way as in claim 1, the subject-matter of claim 21 differs from the disclosure of D5 in that the mold is formed at least in part from a metallic material and has a polished bore, and in that the heat

transfer medium provides temperature control to the mold (10) with a tolerance of about ±0.56 °C to about ±1.11 °C (about ±1 °F to about ±2 °F).

Additionally, claim 21 comprises the features
21.6a, according to which
the mold (10) is a split-mold with hinged halves (11), and
21.6b, according to which
the bore (12) has a polish finish equal to or smaller than about 0.4 microns.

4.2.3 Therefore, the subject-matter of claim 21 involves an inventive step when starting from D5, at least for the same reasons as given above for claim 1.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Moser C. Vetter

Decision electronically authenticated