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**Datasheet for the decision
of 4 November 2014**

Case Number: T 0662/09 - 3.2.08

Application Number: 00300818.2

Publication Number: 1025813

IPC: A61F2/06

Language of the proceedings: EN

Title of invention:

A delivery apparatus for a self-expanding stent

Patent Proprietor:

Cordis Corporation

Opponent:

Boston Scientific Corporation

Headword:

Relevant legal provisions:

EPC Art. 56
EPC R. 99(1)

Keyword:

Admissibility of appeal - (yes)
Inventive step - (yes)

Decisions cited:

G 0001/12, T 0748/09

Catchword:



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Case Number: T 0662/09 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 4 November 2014

Appellant: Boston Scientific Corporation
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
27 February 2009 concerning maintenance of the
European Patent No. 1025813 in amended form.**

Composition of the Board:

Chairman T. Kriner
Members: P. Acton
D. T. Keeling

Summary of Facts and Submissions

- I. The appellant (opponent) filed a notice of appeal, received at the EPO on 3 March 2009, against the opposition division's interlocutory decision, posted on 27 February 2009 finding that, taking into account the amendments made during the opposition proceedings, the European patent No. EP 1 025 813 and the invention to which it relates, met the requirements of the Convention. The appeal fee was paid simultaneously and the statement of grounds was received on 19 May 2009.
- II. Oral proceedings took place before the board of appeal on 4 November 2014.

The appellant requested that the decision under appeal be set aside and that the European patent be revoked.

The respondent (patent proprietor) requested:

- that the appeal be held inadmissible;
- that the appeal, if not inadmissible, be dismissed as unfounded and that the patent be maintained in the form in which it was maintained by the opposition division;
- in the alternative, that the patent be maintained on the basis of one of Auxiliary Requests 1 to 4 filed by letter of 4 September 2014.

- III. Independent claim 1 according to the main request reads:

"A delivery apparatus for a self-expanding stent (1), said apparatus comprising:

a) an outer sheath (40) comprising an elongated tubular member having distal (45) and proximal (42) ends and an inside and outside diameter, said outer sheath having an enlarged section (44) at its distal end (45), said enlarged section having a greater inside and outside diameter than said inside and outside diameter of said sheath proximal to said enlarged section;

b) an inner shaft (10) located coaxially within said outer sheath, said shaft having a distal (14) end and a proximal end (12), said shaft further including a stop (22) attached thereto, said stop being proximal to said distal end of said sheath; and

c) a self-expanding stent (50) located within said enlarged section of said outer sheath, said stent making frictional contact with said outer sheath, said shaft disposed coaxially within a lumen of said stent, whereby said stent makes contact with said stop during deployment of said stent

characterised in that

d) said outer sheath (40) comprises an outer polyamide layer (72), an inner polytetrafluoroethylene layer (48), and a wire reinforcing layer (70) between said inner and outer layers, said reinforcing layer (70) being more rigid than said inner and outer layers."

The auxiliary requests are not relevant for the present decision.

IV. The appellant's arguments can be summarised as follows:

a) Admissibility of the appeal

It was correct that the appellant's name on the notice of appeal was wrong and that the address was missing, contrary to the requirements of Rule 99(1)(a) EPC. However, it was possible to derive from the information in the notice of appeal by whom the appeal should be considered to have been filed. The correction filed with letter of 11 November 2009 did not represent a later change of mind in the sense of paragraphs 29 and 37(b) of G1/12.

Moreover, since the publication number, the application number and the name of the patent proprietor were correctly stated in the notice of appeal, the decision under appeal was clearly identifiable, as required by Rule 99(1)(b) EPC.

Finally, even if the notice of appeal did not define explicitly the subject of the appeal in accordance with Rule 99(1)(c) EPC, it was clear from the whole of the opposition proceedings that the appellant's request was that the impugned decision be set aside and the patent be revoked.

Hence the appeal was admissible.

b) Inventive step

Both starting from D1 and from D3 as closest prior art, the subject-matter of claim 1 as granted was obvious.

Starting from D3

The subject-matter matter of claim 1 differed from the delivery apparatus of D3 only in that the outer sheath comprises an outer polyamide layer and an inner polytetrafluoroethylene layer. In particular, D3 discloses feature (a) since - when referring to the embodiment of Figure 1 - it describes that "the catheter further comprises an optional neck portion located just proximal to the collar" (see column 3, lines 39 to 40).

Since the catheter according to D3 had an outer sheath comprising a braided polymer, it already resisted to kinking and the problem to be solved by the claimed invention was the provision of a catheter with better pushability and reduced friction.

Confronted with this problem, the skilled person would consider the teaching of D16 or D10 and arrive at the subject-matter of claim 1 without the need of any inventive activity.

Starting from D1

Claim 1 did not specify whether the external sheath extended up to the handle of the delivery apparatus, whether it was made of one single piece or it was subdivided in several single pieces, or whether the whole of the sheath was made of the layers as defined in feature (d).

Therefore, the retractable distal sheath (40) shown in Figure 1 of D1 could be considered to represent an outer sheath in the sense of the claimed invention and

the subject-matter of claim 1 differed from the delivery apparatus of D1 only by Feature (d).

The problem to be solved was the provision of a delivery apparatus with a good pushability, a good kinking resistance and low friction when expelling the stent.

A guiding catheter for angioplasty procedures having an outer polyamide layer, an inner polytetrafluorene layer, and a wire reinforcing layer, was known from D16 (see Figure 2; column 3, lines 60 to 65; column 4, lines 3 to 5; column 4, lines 15 to 21) and its combination with the apparatus according to D1 was obvious.

It was also possible to consider the combination of tubular member 49 and outer shaft 10 of D1 to represent the outer sheath according to claim 1. In this case the subject-matter of claim 1 differed from the delivery apparatus according to claim 1 only by the choice of the outer and inner layer of the outer sheath. In order to solve the problem stated above, it would be obvious for the skilled person to apply the teaching of D10 or D16 to the apparatus of D1 and hence arrive at the subject-matter of claim 1 without the need of any inventive activity.

Therefore, the subject-matter of granted claim 1 did not involve an inventive step.

V. The respondent's arguments can be summarised as follows:

a) Admissibility of the appeal

The notice of appeal was filed by "Boston Scientific Limited" while the notice of opposition was filed by "Boston Scientific Corporation", which was a different legal entity. Since according to Article 107 EPC only a party to proceedings adversely affected by a decision could appeal, the appeal was inadmissible for this reason alone.

The correction of the name of the appellant took place with letter dated 11 November 2009, i.e. too late to comply with the requirements of Rule 101(2) EPC and clearly showing a belated change of mind of the appellant.

Moreover, there was no evidence of the true intention as to who was the natural or legal person on whose behalf the appeal was intended to be filed, since the representative did represent both Boston Scientific Corporation and Boston Scientific Limited.

As stated under points 29 and 37 (b) of G 1/12, in the event that the intention was not immediately apparent, the requester bore the burden of proof. In the present case the true intention was not sufficiently substantiated and the correction reflected a later change of mind.

Additionally the appeal was not admissible since none of the provisions of Rule 99 EPC was satisfied.

Since the notice of appeal did not contain the address of the appellant, it did not comply with the requirements of Rule 99(1)(a) EPC.

Moreover, the impugned decision was not correctly identified as required by Rule 99 (1)(b) EPC especially since the date of the decision cited in the notice of appeal was wrong. If it was correct, then the notice of appeal would be late filed.

Finally, not only did the notice of appeal fail to contain the requests defining the subject of the appeal, it did contain a positive statement that the requests would be subject to a separate submission. This corresponded to a clear and unambiguous statement that the requests would be filed later and that no request was present in the notice of appeal, contrary to the requirements of Rule 99(1)(c) EPC.

b) Inventive step

Starting from D3

D3 could not be considered to represent the closest prior art since it failed to disclose Features (a) and (d) of claim 1.

Particularly, neither column 4, lines 39 and 40 nor figure 1 disclosed the relative dimensions of the enlarged section at the distal end as defined in feature (a) of claim 1.

Even assuming D3 to represent the closest prior art, the skilled person had no reason to consider the teaching of D10 or D16 to modify a delivery apparatus for a self-expanding stent, since these documents

referred to guiding catheters, which had a completely different function from that of a stent delivery apparatus.

Starting from D1

Since claim 1 required that the stent was located within the outer sheath (see Feature (c)), only the retractable distal sheath 40 of D1 could be considered to represent an "outer sheath" in the sense of claim 1.

The subject-matter of claim 1 differed from the apparatus according to D1 in that it was made from a multi-layered structure according to Feature (d). The combination of the different layers prevented the stent from becoming too imbedded into the sheath and achieved a radial support, creating sufficient resistance to the outward radial forces of the stent and a reduction of the forces required to deploy the stent (see [0027]). The skilled person would not have taken the teaching deriving from documents dealing with guiding catheters (D10, D16) into consideration for solving the problem stated above, since they had a different function than the claimed apparatus and did not encounter the problem of elongation and necking when the stent was deployed into the vessel.

Hence the subject-matter of claim 1 involved an inventive step.

Reasons for the Decision

1. Admissibility of the appeal

- 1.1 In the opposition as filed, during the opposition proceedings and in the impugned decision, the opponent was identified as Boston Scientific Corporation. However, in the notice of appeal dated 1 April 2009, the appellant was identified as Boston Scientific Limited. Since only the legal entity, which was party to the proceedings at first instance may appeal the decision (Article 107 EPC), Boston Scientific Limited was not entitled to appeal.

The appellant submitted in its letter dated 11 November 2009 that the mention of "Boston Scientific Limited" as the appellant represented an obvious error and was due to an internal oversight of the representative, who was representing in different proceedings both legal entities and that the appeal was filed in the name of Boston Scientific Corporation.

As stated in G 1/12, correction of the name and address of the appellant is allowable under Rule 101(2) EPC if it was the true intention to file the appeal on behalf of the legal person which should have filed the appeal (see answer to question (1)).

In the present case, the representative is the same as the representative of the opponent in the opposition proceedings and the application number and the publication number of the opposed patent, as well as the patentee are correctly mentioned in the notice of appeal. Moreover, the internal reference number of the representative indicated in the notice of appeal is the

same as the one used in the representative's case in opposition proceedings.

It is correct that G1/12, when summarising the case law relevant to corrections under the first sentence of Rule 139 EPC, states under point 37(b) that where the original intention is not immediately apparent, the requester bears the burden of proof, which must be a heavy one. However, in the present case, the Board considers the discrepancy between the registered opponent and the mentioned appellant as an error and holds that sufficient elements are provided in order to identify the true appellant and to establish that the true intention was to file the appeal in the name of the opponent in the first instance proceedings.

Moreover G1/12 states under point 38 that if a correction is allowed under Rule 139 EPC (as in the present case) the condition posed by Article 107 EPC will have been satisfied within the two-month period according to Article 108, first sentence EPC. Hence, the fact that the correction was filed only on 11 November 2009, i.e. after the grounds of appeal and after the error was pointed out by the respondent does not have any impact on the admissibility of the appeal.

1.2 Rule 99 (1) (a) EPC

The respondent pointed out that the notice of appeal did not comply with the requirements of Rule 99(1) (a) EPC since the appellant's address was missing.

It is standard case law that the provisions of Rule 99(1) (a) EPC are satisfied if the notice of appeal contains sufficient information for the identification of the party. In the present case, since the number of

the contested patent and the name and address of the professional representative were the same as those cited in the previous proceedings, it was indeed possible to identify the appellant and the requirements of Rule 99(1) (a) EPC are met.

1.3 Rule 99 (1) (b) EPC

Rule 99(1) (b) EPC requires that the notice of appeal contains "an indication of the decision impugned". In the present case, the notice of appeal correctly designates the patent in suit by its application number and its publication number. It also contains the name of the patent proprietor.

It is correct that the date 15 January 2009 used in the notice of appeal is not the date of the decision but rather the date of the oral proceedings during which the decision was announced. However, since this information is not in contradiction with the data referring to the patent in suit, the whole of the information contained in the notice of appeal is coherent in itself and sufficient to define unequivocally the impugned decision.

1.4 Rule 99 (1) (c) EPC

Rule 99(1) (c) EPC requires that the notice of appeal contains "a request defining the subject of the appeal". The appellant's initial request has to define the subject of the appeal and thereby the framework of the appeal proceedings. As a rule, the notice of appeal should already clarify whether the decision under appeal is contested as a whole or partially, and define the extent of the issues raised in the appeal proceedings.

The absence of such a statement rarely presents a problem in appeals filed by an opponent. As a rule, an opponent would request that the impugned decision be set aside and the patent be revoked either partially or in its entirety (see Case Law of the Boards of Appeal, 7th edition, IV.E.2.5.2). The extent of the request made in an appeal can be inferred by interpreting the notice of appeal in an objective way (Case Law of the Boards of Appeal, 7th edition, IV E 2.5.2 c)), even when the notice of appeal contains no express statement in this respect.

In the present case, the notice of appeal indicates that it is filed against the decision of the opposition division. From the decision itself, it is clear that said decision is only directed to the maintenance of the patent in amended form. Consequently, no request for setting aside only a part of that decision can be assumed (see also T748/09).

Therefore, based on the notice of appeal, the Board has no doubt about the subject of the appeal as being the setting aside of the impugned decision and the revocation of the patent in its entirety. Hence the requirements of to Rule 99(1)(c) EPC are met.

1.5 It follows from the above considerations that - contrary to the respondent's argumentation - the appeal is admissible.

2. Inventive step

2.1 Closest prior art

2.1.1 D3

D3 relates to a delivery apparatus for a self-expanding stent (see abstract and column 3, lines 36 to 37). Its distal end, as shown in Figure 1, is described in column 4, lines 39 and 40 comprises a stent located within the distal sheath 40. Since Figure 1 illustrates sections of the different parts of the distal end only as lines without any recognisable thickness, it does not show clearly and unambiguously a specific ratio between the diameters of the enlarged section of the distal end and the portion proximal thereto as required by Feature (a). The corresponding part of the description (see column 4, lines 39 to 42) only specifies that an "optional neck portion 62" with a slight reduction in diameter may be optionally located just behind the collar 55 which is adjacent to the distal sheath 40. However, this does not amount to specifying that the inside and outside diameters of the sheath 40 are greater than the inside and outside diameters of the neck portion 62. Therefore, D3 does not disclose Feature (a) of claim 1.

Moreover, D3 undisputedly does not disclose a sheath comprising all layers described in Feature (d) of claim 1.

Hence, the subject-matter of claim 1 differs from the delivery apparatus of D3 by Features (a) and (d).

2.1.2 D1

D1 relates to a delivery apparatus for a self-expanding stent (see column 1, lines 6 to 10).

The appellant argues that since claim 1 does not require that the outer sheath extends along the whole delivery apparatus, or that the whole sheath is made of the three-layered structure as described in Feature (d), both the proximal slide sheath 49 in combination with the outer shaft 10 and the distal sheath 40 could be considered to represent the outer sheath in the sense of claim 1.

However, claim 1 as granted requires that the self-expanding stent is located within the enlarged section of the outer sheath (see first sentence of Feature (c)). Since the proximal slide sheath (49) of D1 does not house the stent, the only portion of the apparatus disclosed in D1 which can be considered to represent the enlarged section of claim 1 is the distal sheath 40.

Hence D1 discloses (see particularly Figure 1):

A delivery apparatus for a self-expanding stent, said apparatus comprising:

a) an outer sheath (distal sheath 40) comprising an elongated tubular member having distal and proximal ends and an inside and outside diameter, said outer sheath having an enlarged section (40) at its distal end, said enlarged section having a greater inside and outside diameter than said inside and outside diameter of said sheath proximal to said enlarged section (see enlarged view in Figure 3);

b) an inner shaft (15) located coaxially within said outer sheath, said shaft having a distal end and a proximal end, said shaft further including a stop (53) attached thereto, said stop being proximal to said distal end of said sheath; and

c) a self-expanding stent (35) located within said enlarged section of said outer sheath, said stent making frictional contact with said outer sheath, said shaft disposed coaxially within a lumen of said stent, whereby said stent makes contact with said stop during deployment of said stent.

Therefore, the subject-matter of claim 1 differs from the apparatus of D1 by Feature (d).

2.2 The closest prior art for assessing inventive step is normally a document disclosing subject-matter conceived for the same purpose and having the most relevant technical features in common as the claimed invention.

Since D1 has more features in common with the claimed invention than D3, it represents the closest prior art in the present case.

2.3 Starting from the delivery apparatus of D1, the object to be achieved by the present invention can be seen in providing a delivery apparatus where the stent does not become too imbedded into the sheath, where a radial support is created which provides sufficient resistance to the outward radial forces of the stent and where the forces required to deploy the stent are reduced (see [0027]).

2.4 It is correct that D10 and D16 disclose catheters with sheaths made of a three-layer structure according to

Feature (d). However, contrary to the appellant's arguments, the skilled person would not take these documents into consideration for solving the problem stated above. D10 and D16 both relate to guiding catheters which are inserted into the blood vessels before the catheter which delivers the stent. Therefore, they have to comply with requirements which are different from those of a delivery apparatus for self-expanding catheters. In particular they do not have to face the issue of elongation and of necking created in the sheath when the stent is deployed into the vessel.

Since there is no indication why the skilled person would consider the teaching of D10 or D16 to solve the problem stated above and make the outer sheath of D1 of a layered structure according to Feature (d), the combination of D1 with D10 or D16 cannot lead in an obvious way to the subject-matter of claim 1 of the present main request.

- 2.5 The same argumentation would apply mutatis mutandis even if D3 were considered to represent the closest prior art and was combined with the D10 or D16.
- 2.6 Therefore, the subject-matter of claim 1 involves an inventive step

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



V. Commare

T. Kriner

Decision electronically authenticated