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**Datasheet for the decision
of 17 April 2019**

Case Number: T 0089/16 - 3.2.08

Application Number: 09165444.2

Publication Number: 2119415

IPC: A61F2/06

Language of the proceedings: EN

Title of invention:
Helical stent design

Patent Proprietor:
Boston Scientific Limited

Opponents:
Cordis Corporation
C.R. Bard

Headword:

Relevant legal provisions:
EPC Art. 56
RPBA Art. 12(2), 12(4)

Keyword:

Inventive step - main request (no) - reformulation of the technical problem - obvious modification
Late-filed request - request not examined by the examining division - not to be taken into account because requirements of Article 12(2) RPBA not fulfilled

Decisions cited:

T 1890/09, T 0892/08

Catchword:



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Case Number: T 0089/16 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 17 April 2019

Appellant: C.R. Bard
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 5 November 2015
rejecting the opposition filed against European
patent No. 2119415 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairwoman P. Acton
Members: C. Herberhold
 Y. Podbielski

Summary of Facts and Submissions

- I. By decision posted on 5 November 2015 the opposition division rejected the opposition against European patent No. EP-B-2119415.
- II. Opponent 2 (appellant) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.
- III. In accordance with the appellants and respondents requests the Board issued a summons for oral proceedings, followed by a communication dated 10 December 2018.
- IV. With letters dated 12 April 2019 (appellant), 15 January 2019 (respondent) and 10 April 2019 (opponent 1, party as of right) the parties to the appeal proceedings indicated that they would not be attending the oral proceedings.
- V. In accordance with the provisions of Rule 115(2) EPC and Article 15(3) RPBA, the proceedings took place on 17 April 2019 in the parties' absence.
- VI. The requests submitted by the parties in writing were as follows:

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

The respondent requested that the appeal be dismissed and the patent be maintained as granted, or, as an auxiliary measure, that the patent be maintained on the basis of one of auxiliary requests 1 to 9 submitted

during first instance proceedings with submission of 7 September 2015 and filed in the appeal proceedings with the reply to the statement setting out the grounds of appeal.

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

"A stent (10) for implantation in a body lumen, the stent having an open-ended tubular shape defined by a structure comprising:
at least one continuous elongated helical band element (11) comprised of spaced undulating portions (12) forming end loop portions (13), wherein adjacent undulating portions of the helical element are out of phase, the helical band element extending substantially over the length of the stent body, and
a plurality of curvilinear elements (14) extending between and interconnecting at least some of the adjacent, undulating portions of the helical element over its length, **characterized in that** the curvilinear interconnecting elements are attached to locations of the undulating portions other than the extreme ends."

VIII. Auxiliary requests 1-9

The detailed wording of auxiliary requests 1-9 has no bearing on the present decision.

IX. The following document played a role in the present decision:

D3 WO 98/30173

- X. The essential arguments of the appellant can be summarised as follows:

Main request - lack of inventive step

The opposition division had argued that the subject-matter of claim 1 of the main request differed from the disclosure of D3 in that the curvilinear interconnecting elements were attached to locations of the undulating portions other than the extreme ends. This allegedly resulted in exhibiting enhanced flexibility while reducing the risk of breaking. There was however not a shred of evidence for that effect. Indeed, with the patent being silent as to how the attachment of the connector on a location of the undulating portions other than its extreme end had to be configured, it was highly likely that the claimed effect would not occur over the entire breadth of the claim.

Hence, the only effect present over the entire breadth of the claim was the effect of providing an alternative to the attachment of the connectors at the extreme ends of the undulating portions. With the only alternative being to have the interconnecting elements attached to locations of the dilated portions other than the extreme ends, no inventive step was involved.

Auxiliary requests 1-9

The appellant did not submit any arguments with respect to the auxiliary requests.

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

Main request - Inventive step

The respondent essentially agreed with the analysis of the opposition division starting from D3 as closest prior art. As already made clear during oral proceedings before the opposition division, the attachment at locations other than the extreme ends of the undulating portions reduced stresses being present in the stent at the extreme ends of the undulating portions. While, for example, during expansion the undulating portions considerably deformed at the extreme ends in order to allow for the required increase in diameter of the stent, the stresses imparted by the curvilinear connectors to the undulating portions were introduced at locations away from the extreme ends of the undulating portions so that the focus of stresses at these extreme ends was considerably reduced and the risk of breaking was lowered.

There was no reason whatsoever for the skilled person to turn to any of the remaining prior art documents which were cited during the first instance proceedings but which were no longer cited during the present appeal proceedings.

The appellant's attempt to characterize the distinguishing feature as not having any technical effect was improper in view of the above explanations so that the subject-matter of claim 1 of the main request was not only novel but also based on an inventive step vis-à-vis the cited prior art.

Auxiliary requests 1-9

Auxiliary requests 1-9 addressed in various forms the attacks raised by the appellant.

Reasons for the Decision

1. Main request - inventive step
- 1.1 The Board agrees with the opposition Division and the parties that D3 forms a suitable closest prior art.
- 1.2 D3 discloses:

A stent (Figures 1 and 5a) comprising:

one continuous elongated helical element (page 6, lines 25-27), the continuous elongated helical element having undulating portions (15) forming a serpentine configuration and extending substantially over the length of the stent body, wherein adjacent undulating portions are out of phase (page 8, lines 23-25); and

a plurality of curvilinear connectors (Figure 5a, 38a), the curvilinear connectors extending between and interconnecting at least some of the adjacent undulating portions (15).

- 1.3 It is undisputed that the subject-matter of claim 1 differs from the disclosure of D3 (see Figure 5a) in that

"the curvilinear connectors are attached to locations on the undulating portions other than the extreme ends of the undulating portions".

1.4 According to the patent specification, the problem solved by the patent is to provide a "flexible, conformable stent which expands uniformly and provides good radial strength, scaffolding and fatigue characteristics when expanded" (paragraph [0011] of the patent).

However, according to the original disclosure, the embodiments of the invention - which evidently have to solve the problem posed - comprise "a plurality of curvilinear, most preferably sinusoidal, connectors extending between and interconnecting at least some of the adjacent undulating portions, preferably connected to the end loop portions, of the helical element over its length" (page 3, first paragraph). This is likewise stated in the patent specification itself (column 2, lines 42-47). Said disclosure is further in accordance with the passage on page 4, lines 6-9 of the description as originally filed, which states that "the interconnecting elements 14 preferably join end portions 13 at their extreme ends and extend directly between longitudinally spaced adjacent end portions", while acknowledging that "the connectors may be attached to other locations on the undulations other than the extreme ends".

From these passages it has to be deduced that whether the interconnecting elements "join the end portions at their extreme ends" or whether "they are attached to other locations on the undulations other than the extreme ends" is of no relevance for solving the problem posed in the patent. Thus, the problem formulated in the patent is, indeed, solved by the stent disclosed in D3 (in which the interconnecting elements join the undulating portions at their extreme ends) as well as by the stent defined in claim 1 (in

which the interconnecting elements are attached to locations on the undulating portions other than the extreme ends).

In this context it is irrelevant that D3 explicitly mentions a further, different problem to be solved (see point 5.4. of the impugned decision). A further problem solved does not change the fact that the stent disclosed in D3 has all the features of a stent which is disclosed to solve the problem posed in the patent in suit and in the original application.

With the technical problem posed being solved by the stent according to prior art D3, an alternative, less ambitious problem needs to be formulated, i.e. to provide an alternative solution to the problem posed.

- 1.5 D3 discloses on page 8, lines 18-20 that as an alternative, the "bridges could be interconnected between adjacent windings midway between bends on each adjacent winding, with consistent corresponding placement of the remaining bridges", i.e. D3 discloses an alternative stent design in which the curvilinear connectors are attached to locations on the undulating portions other than the extreme ends.

In the context of the technical problem being simply to provide an alternative to the prior art, features already conventional in the art for the product (such as the one disclosed on page 8, lines 18-20) represent an equally suggested or obvious solution to the posed problem (see in this context e.g. T892/08, reasons 1.7 with references to further cases).

Consequently, the subject-matter of claim 1 is obvious.

1.6 The proprietor and the opposition division have pointed out that the attachment at locations other than the extreme ends of the undulating portions reduced stresses being present in the stent at the extreme ends, thereby lowering the risk of breaking of the stent.

However, the patent and the application from which it derives are completely silent on any stress development in the extreme ends and of any breaking risk at these locations. Fatigue characteristics are referred to on page 2 , lines 14-16 of the application as filed (column 2, lines 25-29 of the patent specification), but as mentioned above, according to the original disclosure any favourable effect in this respect is present whether the curvilinear elements are attached to locations of the undulating portions other than the extreme ends or not.

The problem allegedly solved is thus not derivable from the application as filed and cannot establish the presence of an inventive step.

1.7 One could - for the sake of the argument - assume that the skilled person was sufficiently gifted to immediately recognize from the patent specification that attaching the curvilinear elements to locations of the undulating portions other than the extreme end portions results in inducing part of the forces at a location away from the extreme end portions, thereby reducing local stress and the risk of breaking at these extreme end portions.

Then one had, however, to assume that the skilled person was as well gifted enough to recognize the identical technical effect and problem solved from the

alternative disclosed in prior art D3, page 8, lines 18- 20, in which the connectors are likewise attached at a location away from the extreme end portions of the undulating portions.

Attaching the curvilinear elements to locations other than the extreme end portions will then, again, be an obvious solution to the problem derived by the respondent and the opposition division.

- 1.8 Either way, the Board comes to the conclusion that the subject-matter of claim 1 of the main request does not involve an inventive step.
2. Auxiliary requests 1-9
 - 2.1 The respondent filed auxiliary requests 1 to 9 with the reply to the statement setting out the grounds of appeal. The only explanation given is that these requests are filed as an auxiliary measure and address in various forms the attacks raised by the appellant. No further submissions were made on this issue at any other point in the proceedings, neither in writing nor orally (the respondent did not participate to the oral proceedings).
 - 2.2 Article 12(2) of the Rules of Procedure of the Boards of Appeal (RPBA) provides that both the grounds of appeal and the reply thereto must contain a party's complete case. They must set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld, and must specify expressly all the facts, arguments and evidence relied on. The reason for requiring the parties to present their complete case at the earliest stage of the proceedings is to ensure a fair procedure, where both

parties know from the outset the case they have to meet, and to enable the Board to commence its work on the basis of these submissions.

2.3 By filing the auxiliary requests the respondent requested in effect that the decision under appeal be amended so that the patent be maintained on the basis of one of these requests. Pursuant to the principle underlying Article 12(2) RPBA that a party is to present its entire case at the outset of the proceedings it was for the respondent to provide arguments as to why these amended sets of claims overcame the objections raised by the opponent against the main request.

2.4 There may be exceptional circumstances where the Board does not require such arguments, namely where it is immediately apparent to the Board why the new request overcomes the objections. An example of such a case is where the patentee files an auxiliary request in which a feature which has been objected to under Article 123(2) EPC is amended in such a way that it is immediately apparent to the Board that the objection has been overcome. However, in the present case no such exceptional circumstances exist.

2.5 The opponent had raised various objections against the main request under Articles 100(a) and (c) EPC, including lack of inventive step. The respondent has not provided any arguments on the patentability of the subject-matter of claim 1 of any of the auxiliary requests, and thus on why these requests overcome the objections made by the opponent against the main request.

2.6 In view of the above, the Board concludes with regard to auxiliary requests 1-9 that the respondent has not complied with Article 12(2) RPBA. Pursuant to Article 12(4) RPBA the Board does not take these requests into account (see also T 1890/09, Reasons 4).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated