Datasheet for the decision
of 17 April 2019

Case Number: T 0073/16 - 3.2.08
Application Number: 10177524.5
Publication Number: 2305175
IPC: A61F2/90
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 opposition 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:
Case Number: T 0073/16 - 3.2.08

DEVELOPMENT

of Technical Board of Appeal 3.2.08

of 17 April 2019

Appellant: C.R. Bard
(Opponent 2)
730 Central Avenue
Murray Hill, NJ 07974 (US)

Representative: Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München (DE)

Respondent: Boston Scientific Limited
(Patent Proprietor)
Clarendon House
2 Church Street
Hamilton HM11 (BM)

Representative: Vossius & Partner
Patentanwälte Rechtsanwälte mbB
Siebertstrasse 3
81675 München (DE)

Party as of right: Cordis Corporation
(Opponent 1)
430 Route 22
Bridgewater, NJ 08807 (US)

Representative: Prock, Thomas
Marks & Clerk LLP
15 Fetter Lane
London EC4A 1BW (GB)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
Composition of the Board:

Chairwoman  P. Acton
Members:  C. Herberhold  Y. Podbielski
Summary of Facts and Submissions

I. By decision posted on 6 November 2015 the opposition division decided that European patent No. 2 305 175 as per the main request filed during oral proceedings, and the invention to which it related, met the requirements of the EPC.

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 appellant's and respondent's 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 that the patent be revoked.

The respondent requested to dismiss the appeal, i.e. maintenance according to the main request as submitted during oral proceedings before the opposition division
on 13 October 2015, or, as an auxiliary measure, maintenance of the patent on the basis of one of auxiliary requests 1 or 2 filed on 20 September 2019 with the reply to the statement setting out the grounds of appeal.

VII. Claim 1 of the main request reads as follows:

"A stent (10) comprising:

one continuous elongated helical element (11), the continuous elongated helical element having undulating portions (12) forming a serpentine configuration and extending substantially over the length of the stent body, wherein adjacent undulating portions are out of phase; and

a plurality of curvilinear connectors (14), the curvilinear connectors extending between and interconnecting at least some of the adjacent undulating portions (12),

characterized in that

the curvilinear connectors (14) are attached to locations on the undulating portions other than the extreme ends of the undulating portions."

VIII. Auxiliary request 1, claim 1

The subject-matter of claim 1 of auxiliary request 1 comprises the following amendment with regard to the subject-matter of the main request:

"A stent (10) formed from a tube comprising:..."
IX. Auxiliary request 2, claim 1:

The subject-matter of claim 1 of auxiliary request 2 comprises the following additional feature with regard to the subject-matter of claim 1 of auxiliary request 1:

"...and the curvilinear connectors (14) extend between longitudinally spaced helical portions from and to longitudinally directly adjacent loop end portions (13) which are diagonally spaced from each other".

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

D3: WO 98/30173

XI. 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 of the undulating portions, no inventive step was involved.

*Auxiliary requests 1 and 2*

The amendment in claim 1 of auxiliary request 1 did not make its subject-matter inventive. As to auxiliary request 2, the proprietor had failed to specify why claim 1 of the second auxiliary request would be novel and/or inventive.

XII. 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 and 2**

The amendment in auxiliary requests 2 was deemed to even further distinguish the claimed subject-matter from both D3 and D4. The respondent did not provide comments as to the patentability of the subject-matter of auxiliary request 1.

**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 [0009] 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 33-38). 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 end portions.

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. T 892/08, 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 end portions, 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 of the undulating portions 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 6-10 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 end portions
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

2.1 The respondent filed auxiliary requests 1 and 2 with the reply to the statement setting out the grounds of appeal. It identified in the reply to the statement setting out the grounds of appeal the amendments to claim 1 of each request compared to claim 1 of the main request, and specified where support for these amendments could be found in the application as filed. However, it made no submissions on the patentability of the subject-matter of the set of claims of auxiliary request 1, and with regard to the subject-matter of the set of claims of auxiliary request 2 it merely stated that “this amendment is deemed to even further distinguish the claimed subject-matter from both D3 and D4.” 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 that the decision under appeal be amended. Pursuant to Article 12(2) RPBA 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 auxiliary request 1, and thus on why the request overcomes the objections made by the opponent against the main request.

2.6 As regards auxiliary request 2, the Board notes that the respondent stated that the amendment was intended to further distinguish the claimed subject-matter from D3 and D4. Whilst the Board agrees with the respondent that the amendment does have this effect, the Board is nevertheless not in a position to derive therefrom that the claimed subject-matter is inventive. When
considering inventive step, there are several other relevant factors to consider such as the objective technical problem and obviousness. The lack of argument in this respect means that the Board is not in a position to understand why the respondent considers that the request overcomes the objections made by the opponent against the main request.

2.7 In view of the above, the Board concludes that with regard to both auxiliary requests 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