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**Datasheet for the decision
of 13 September 2011**

Case Number: T 1178/09 - 3.2.08

Application Number: 01830489.9

Publication Number: 1277449

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:
Stent

Patentee:
SORIN BIOMEDICA CARDIO S.R.L.

Opponent:
Conor Medsystems, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 100(b), 100(a)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Sufficiency of disclosure (yes)"
"Novelty and inventive step (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 1178/09 - 3.2.08

D E C I S I O N
of the Technical Board of Appeal 3.2.08
of 13 September 2011

Appellant:
(Opponent)

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Representative:

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Respondent:
(Patent Proprietor)

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Representative:

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Decision under appeal:

Interlocutory decision of the Opposition
Division of the European Patent Office posted
2 April 2009 concerning maintenance of European
patent No. 1277449 in amended form.

Composition of the Board:

Chairman: T. Kriner
Members: R. Ries
E. Dufrasne

Summary of Facts and Submissions

- I. Opposition was filed against European patent No. 1 277 449 as a whole by the present appellant.

In its interlocutory decision dispatched on 2 April 2009, the opposition division held that the subject matter of the claims according the first auxiliary request (filed as auxiliary request II) then on file met the requirements of the EPC and that the patent could be maintained in amended form on the basis of this request.

- II. The appellant (opponent) lodged an appeal against this decision on 2 June 2009 and the appeal fee was paid on the same date. The statement setting out the grounds of appeal was received on 28 July 2009.

- III. For the present decision, the following documents have played a role:

D2: US-B-6 254 632

D3: EP-A-0 950 386

D4: WO-A-99/49928

- IV. Oral proceedings were held before the Board on 13 September 2011.

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

The respondent (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request filed

during the oral proceedings or, in the alternative, of one of the auxiliary requests 1 to 5 filed with letter dated 10 August 2011.

V. Independent claim 1 of the main request read as follows:

"1. A stent (1) comprising a radially expandable tubular body made up of elements (2, 3) defining a reticular structure, said elements (2, 3) comprising a plurality of annular elements (2) having a roughly cylindrical shape and a serpentine pattern, aligned in sequence along the main axis of the stent, wherein said annular elements (2) are connected together by means of longitudinal connection elements (3), said elements (2, 3) constituting respective branches of the structure, wherein said elements (2, 3) are at least locally provided with recesses (4) for the reception of agents for the treatment of the site of implant of the stent, said recesses conferring on the respective element (2, 3), where said recesses are present, a hollowed sectional profile, of which said recesses (4) occupy a substantial portion; the geometry of said recesses (4) being such as to leave substantially unimpaired the characteristics of bending strength ($l_x, l_y,$) of the respective element (2, 3), wherein said recesses (4) are present in a discontinuous way on said elements (2, 3) of said stent, (1), and wherein said recesses (4) are provided both on said annular elements (2) and said longitudinal connection elements (3), characterised in that the recesses are placed in such a way as to avoid recesses (4) being located in the areas of said elements subjected to deformation during the deformation of said stent, and said recesses (4) are exclusively made in areas corresponding to rectilinear

or substantially rectilinear portions of said elements (2, 3)."

Dependent claims 2 to 14 relate to preferred embodiments of the stent set out in claim 1.

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

Articles 100(b), 83 EPC:

In its pre-characterising part, claim 1 required that the geometry of the recesses (4) should be selected such as to leave substantially unimpaired the characteristics of the bending strength (l_x , l_y) of the respective elements (2, 3). This implied that the design of the recesses represented an important feature to satisfy this condition. However, the patent specification did not provide the skilled reader with any specific technical information as to how the geometry should look for the recesses in order to leave substantially unimpaired the characteristics of the bending strength (l_x , l_y). Hence the patent did not disclose the claimed subject matter sufficiently clearly and completely for it to be carried out by a person skilled in the art.

Articles 100(a), 54, 56 EPC:

Novelty:

Document D4, in particular page 9 in conjunction with Figure 2, disclosed a cylindrical stent having axial struts (28) and a plurality of rows of axial slots (22).

Additional circumferential slots (26) were provided at the ends of the axial slots. Like the stent claimed in the patent, the known stent thus comprised

a) serpentine annular elements made of rigid struts (28) and circumferential links (30) at the axial ends of the stent and the axial outer portions of the circumferential links (30) in the middle of the stent, interconnected with the struts (28) by ductile hinges (reduced sections 32), and

b) longitudinal connecting elements (consisting of the central portion of the circumferential links 30).

Claim 1 did not require that the elements a) and b) must be separate elements. As disclosed in D4, page 25, first paragraph, the rigid axial struts (28), but not the deforming hinges (32) or (66) shown in Figure 8, could be provided with laser-drilled holes containing a beneficial therapeutic agent. Consequently, the subject matter of claim 1 was anticipated by the disclosure of document D4 and therefore not novel.

Inventive step:

In case novelty should be acknowledged, the claimed stent at least did not involve an inventive step. A difference between the claimed stent and the closest prior art D4, Figure 2 could be seen in the fact that D4 provided laser-drilled holes for carrying a beneficial agent only in the axial struts (corresponding to the claimed annular elements (2)) but not in the circumferential links (30), which correspond to the longitudinal connecting elements (3) of the claimed stent. Given that only the hinges (32), (66) were deformed when the stent was expanded, as shown in D4, Figure 8, the struts and the circumferential links

remained substantially un-deformed. Faced with the problem of increasing the charge of therapeutic agent to be carried by the stent, it was close at hand for the person skilled in the art also to provide the circumferential links with laser-drilled holes.

Moreover, the stent embodiment depicted in Figures 4a and 4b of document D4 comprised separate connecting S-shaped bridging elements (84) which allowed the stent to bend when passing through the path of the vasculature. In order to solve the above mentioned problem, the skilled person would, without inventive thinking, also provide the rectilinear part of the bridging elements (84) with laser-drilled holes or recesses. The subject matter of claim 1 was therefore obvious from the disclosure of document D4 alone.

Assuming that the stent known from D4, Figure 2 did not include longitudinal connection elements, the problem to be solved when starting from D4 could be seen in providing a longer stent. This problem was solved by combining the teaching of D4 with the stent design disclosed in document D2, in particular figures 1 and 6b. These figures showed rectilinear longitudinal connecting struts (104) which were disposed between the adjacent cylindrical struts (102) and which were provided with recesses (622) as shown in D2, Figure 6b. Drilling recesses in the longitudinal connecting elements was therefore obvious from document D2.

In addition thereto, the intravascular stent disclosed in document D3, Figure 4 comprised annular formed struts connected by longitudinal elements. The latter were provided with recesses (reservoirs 45) created in

the curved parts. Given that only the connection area between the strut elements was deformed when the stent was expanded, whereas the curved parts remained undeformed, this requirement for the claimed stent set out in the characterising part of claim 1 was met. Should the charge of therapeutic agent be increased, the skilled person would in an obvious manner also provide the longitudinal parts of the struts with such recesses.

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

Articles 100(b), 83 EPC:

As to the geometry of the recesses, the appellant tried to create a contradiction between the claims and the description. The recess geometry was, however, not a key feature of the invention. In the light of the description, claim 1 merely required that the shape and size of the recesses should be chosen such as not to jeopardise the characteristics of flexural strength of the hollowed-out elements. To this end, in accordance with the description, paragraph [0063], the sectional areas could be "oversized" to prevent impairment of the structural strength. Based on the patent specification and the embodiments shown in Figures 2 and 3, which represented a solution according to the invention, the claimed stent could be put into practice without difficulty by a person skilled in the art. Article 100(b) EPC was therefore satisfied.

Articles 100(a), 54, 56 EPC:

Novelty:

Document D4 merely taught on pages 24 and 25 that the struts (28), due to their large size, could be provided with laser-drilled holes for drug delivery. There was no disclosure that the thin longitudinal connecting elements or any other parts of the stent could comprise such holes. Novelty was therefore given already for this reason.

Inventive step:

None of documents D4, D3 or D2 taken individually or in combination would make the claimed stent obvious. Document D4, Figure 2 showed a stent consisting of one single tubular element comprising axial struts (28) and circumferential links (30). The device of document D4 represented a totally different stent design which was not comparable with the claimed stent structure featuring in the preamble of claim 1. Therefore, D4 could not be regarded as representing the closest prior art. The stent shown in D3, Figure 4 comprised recesses (reservoirs (45) to hold the drug to be delivered) which were located in the cusp areas. Hence the disclosure of D3 was directly opposite to the teaching of the patent in suit, according to which recesses in the curved parts of the sinusoidal path of the elements were avoided. The same argument was true for the stent shown in D2, Figure 6b showing a high concentration of recesses (622) in the cusp areas. Neither D4 nor D3 nor D2 gave any information or hint to solve the problem addressed in patent, i.e. to avoid the presence of

recesses in the deformed cusp areas or curved portions of the stent so that the flexural strength of the annular and longitudinal elements was not impaired.

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

Reasons for the Decision

1. The appeal is admissible.
2. Article 100(b) EPC:

Claim 1 of the main request defines a stent having a reticular structure made up of annular elements (2) of a cylindrical shape and a serpentine pattern which are connected by the longitudinal connection elements (3). Recesses, used for the reception of agents for the treatment of the site of implant of the stent, are located exclusively in the rectilinear or substantially rectilinear portions of the elements (2, 3). The geometry of the recesses is to be chosen such that the bending characteristics of the elements (2, 3) are not adversely affected and the characteristics of structural strength of the parts constituting the stent are not substantially impaired. In the light of the description it is clear that not the geometry of the recesses alone is of importance, but that the geometry of the recesses and of the elements where the recesses are arranged have to be considered. In this respect, paragraph [0063] of the patent specification teaches that the sectional area of the elements comprising the recesses could be "oversized" to guarantee sufficient

stability. Further, the wording of claim 1 makes it clear that areas which undergo deformation e.g. by bending, when the stent is being navigated through the vasculature to the desired implantation site, or when it is being expanded, are kept free of recesses. Figures 2 and 3 of the patent specification illustrate two embodiments of the claimed stent which teach the skilled reader how the claimed stent could be put into practice. Contrary to the appellant's allegations, the patent specification therefore provides the person skilled in the art with sufficient technical information to put the claimed stent into practice without undue effort.

Therefore the ground of Article 100(b) EPC does not succeed in respect of the main request.

3. Articles 100(a) and 54 EPC; novelty

The central plank on which the appellant based its ground of lack of novelty was document D4, Figure 2 in combination with the explanations given on corresponding page 9.

The Board cannot share the appellant's view for the following reasons. The tissue-supporting stent shown in D4, Figure 2 consists of a single annular element having axial struts (28) connected by circumferential links (30). Since there is only one single annular element, the stent according to Figure 2 of D4 has no longitudinal connection elements. The appellant's view that the circumferential links (30) in the middle of the stent can be split up into three different elements so that the axial outer portions form part of two

independent annular elements, and the portion between these outer portions forms longitudinal elements connecting these annular elements, is artificial and completely based on hindsight. The circumferential links (30) are made of a single piece for connecting the axial struts (28) and cannot be regarded as forming three separate independent elements for different purposes.

Moreover, even if the stent according to Figure 2 of D4 was regarded as comprising a plurality of annular elements and longitudinal connecting elements, it would not comprise all the features of the stent according to claim 1. As set out on page 24, last line, to page 25, line 5, of document D4, the axial struts (28), due to their large size, could be provided with laser-drilled holes which can be used for beneficial agent delivery. However, document D4 does not disclose that the circumferential links (30), which in the appellant's view correspond to the longitudinal connection elements (3) of the claimed stent, are also provided with holes or recesses. Moreover, there is no teaching in this document that areas of the stent which undergo deformation should be kept free of recesses or holes. Hence the subject matter of claim 1 is not anticipated by document D4 and is, therefore, novel.

4. Articles 100(a) and 56 EPC; inventive step

4.1 The appellant argued that the claimed subject matter was obvious for a person skilled in the art from the teaching of document D4 alone. Faced with the problem of increasing the amount of a desired therapeutic agent to be delivered by the stent of document D4, it was

obvious for a skilled person also to provide also the circumferential links (30) with recesses (holes) as an additional reservoir.

In a second line of argument, the appellant referred to the stent disclosed in D4, Figures 4a and 4b, which additionally comprised S-shaped bridging elements (84) connecting the cylindrical tubes (82). The elements (84) were regarded as corresponding to the longitudinal connecting elements (3) set out in claim 1 of the patent at issue. The appellant alleged that it was close at hand also to provide the rectilinear parts of the S-shaped bridging elements (84) with recesses in order to increase the amount of drug delivered by the stent.

- 4.2 The Board cannot agree. With respect to the transport of a therapeutic agent, the teaching of document D4 is unambiguously clear: due to their large size only the axial struts (28) are provided with recesses or holes since there is enough space for doing so. There is no information in D4 implying that also other parts of the stent could be used for drug delivery. Arguing that other parts of the stent could also be provided with recesses can be done only by hindsight, i.e. in the knowledge of the claimed invention.

As to the second line of argument, document D4 teaches on page 15, lines 1 to 8, that the bridging elements (84) provide the stent with an improved axial flexibility and allow the device to bend when passing through the vasculature and to match the curvature of a lumen to be supported. Claim 1 of the patent at issue however requires that areas of the stent which undergo

deformation should be free of recesses to prevent weakening of the stent's strength. Providing the bridging part (84) with recesses would, therefore, mean acting contrary to the teaching of the patent at issue.

4.3 Even if the problem of providing a stent having a length greater than that shown in D4, Figure 2, had to be solved, the combination of the teaching of D4 with that of D2 does not lead in an obvious way to the claimed stent. This is all the more true as the solution to this problem is already given in document D4 by the embodiment shown in Figures 4a and 4b: this stent includes a plurality of cylindrical tubes (82) which are connected by S-shaped bridging elements (84). There is no reason whatsoever to combine the teaching of D4 with that of D2, which refers to a different type of stent. It is to be noted in this context that Figure 6b of D2 shows protrusions (622) located in particular in the curved parts of the stent, which is contrary to the teaching of the patent at issue.

4.4 The appellant further argued that the skilled person, taking into account the periodic and symmetric structure of the stent shown in Figure 4 of D3, would contemplate adding more recesses to the serpentine annular and longitudinal elements, if more of the therapeutic treating agent was to be accommodated. Therefore, the skilled person would be led by the disclosure of D3 in an obvious manner to the subject matter of the patent in suit.

4.5 The Board cannot agree. In particular Figure 4 of D3 shows a stent with reservoirs (45) created at the apex (i.e. in the cusp parts) of a flexible strut. This is

in complete contrast to the teaching of patent at issue. Only on the basis of hindsight could it be argued that the reservoirs (45) should be provided in the rectilinear parts of the serpentine elements and that recesses in the curved parts should be avoided.

Given this situation, the subject matter of claim 1 also involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of claim 1 of the main request filed during the oral proceedings, and claims 2 to 14, description and figures underlying the decision under appeal.

The Registrar:

The Chairman:

V. Commare

T. Kriner