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Datasheet for the decision of 3 April 2014

Case Number: T 1737/12 - 3.2.08

Application Number: 01925368.1

Publication Number: 1261297

IPC: A61F2/06

Language of the proceedings: EN

Title of invention:
INTRALUMINAR PERFORATED RADIALLY EXPANDABLE DRUG DELIVERY PROSTHESIS

Patent Proprietor:
Boston Scientific Scimed, Inc.

Opponent:
CONOR MEDSYSTEMS

Headword:

Relevant legal provisions:
EPC Art. 100(a), 54, 56
RPBA Art. 12(4)

Keyword:
Novelty - main request (yes)
Inventive step - main request (no)
Auxiliary requests - admitted (no)

Decisions cited:

Catchword:

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Case Number: T 1737/12 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 3 April 2014

Appellant: (Patent Proprietor)	Boston Scientific Scimed, Inc. Scimed Life Systems, Inc. One Scimed Place Maple Grove, MN 55311-1566 (US)
Representative:	Vossius & Partner Siebertstrasse 4 81675 München (DE)
Respondent: (Opponent)	CONOR MEDSYSTEMS 1003 Hamilton Court Menlo Park, CA94025 (US)
Representative:	van Loon, C.J.J. Vereenigde Johan de Wittlaan 7 2517 JR Den Haag (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 11 June 2012 revoking European patent No. 1261297 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: T. Kriner
Members: M. Alvazzi Delfrate
D. T. Keeling

Summary of Facts and Submissions

I. By decision posted on 11 June 2012 the opposition division revoked European patent No. 1 261 297.

The opposition division found that the subject-matter of claim 1 as granted did not involve an inventive step in view of

D1: EP-A-0 747 069; and
D11: WO-A-98/30173.

Furthermore, the opposition division did not admit the three auxiliary requests submitted by the patent proprietor during the oral proceedings.

II. The appellant (patent proprietor) lodged an appeal against this decision on 26 July 2012, paying the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 10 October 2012.

III. Oral proceedings before the board of appeal were held on 3 April 2014. As announced by letter of 25 March 2014 the appellant did not attend the oral proceedings, which, in accordance with Rule 115(2) EPC, were continued in its absence.

IV. In the written procedure the appellant requested that the decision under appeal be set aside and the opposition rejected or in the alternative that the patent be maintained on the basis of one of the auxiliary requests 1-3 as filed with letter dated 10 October 2012.

The respondent (opponent) requested that the appeal be dismissed.

V. Claim 1 as granted (**main request**) reads as follows:

"A radially expandable prosthesis for implantation in a lumen comprising a tubular wall produced from sheet metal and showing an inner (3) and an outer surface (2), which tubular wall is provided with cuts forming solid struts (1) having a predetermined thickness (T) and enabling the prosthesis to expand, said solid struts (1) having a longitudinal direction (A) and showing reservoirs (4) made in said outer surface (2) for containing a therapeutic agent, characterised in that at least a number of said reservoirs (4) are formed by perforating holes (4) which extend through the solid strut (1) forming in the outer surface (2) of the tubular wall an outer opening (5) and in the inner surface (3) of the tubular wall an inner opening (6), said outer opening (5) having a width (w) measured perpendicular to said longitudinal direction (A) and a length (I) measured in said longitudinal direction (A) which is substantially equal to said width (w), the prosthesis, including said perforating holes (4), being polished electrochemically so that said cuts have a smooth electrochemically polished surface."

Claim 1 of **auxiliary request 1** reads as follows (emphasis added):

"A radially expendable [sic] prosthesis for implantation in a lumen comprising a tubular wall produced from sheet metal and showing an inner (3) and an outer surface (2), which tubular wall is provided with cuts forming solid struts (1) having a predetermined thickness (T) and enabling the prosthesis to expand, said solid struts (1) having a longitudinal direction (A) and showing reservoirs (4) made in said

outer surface (2) for containing a therapeutic agent, characterised in that at least a number of said reservoirs (4) are formed by perforating holes (4) which extend through the solid strut (1) and through the prosthesis, forming in the outer surface (2) of the tubular wall an outer opening (5) and in the inner surface (3) of the tubular wall an inner opening (6), said outer opening (5) having a width (w) measured perpendicular to said longitudinal direction (A) and a length (I) measured in said longitudinal direction (A) which is substantially equal to said width (w), the prosthesis, including said perforating holes (4), being polished electrochemically so that said cuts have a smooth electrochemically polished surface."

Claim 1 of auxiliary request 2 reads as follows (emphasis added):

"A radially expendable [sic] prosthesis for implantation in a lumen comprising a tubular wall produced from sheet metal and showing an inner (3) and an outer surface (2) forming the inner and outer surface of the prosthesis which tubular wall is provided with cuts forming solid struts (1) having a predetermined thickness (T) and enabling the prosthesis to expand, said solid struts (1) having a longitudinal direction (A) and showing reservoirs (4) made in said outer surface (2) for containing a therapeutic agent, characterised in that at least a number of said reservoirs (4) are formed by perforating holes (4) which extend through the solid strut (1) forming in the outer surface (2) of the tubular wall an outer opening (5) and in the inner surface (3) of the tubular wall an inner opening (6), said outer opening (5) having a width (w) measured perpendicular to said longitudinal direction (A) and a length (I) measured in said

longitudinal direction (A) which is substantially equal to said width (w), the prosthesis, including said perforating holes (4), being polished electrochemically so that said cuts have a smooth electrochemically polished surface."

Claim 1 of auxiliary request 3 reads as follows (emphasis added):

"A radially expendable [sic] prosthesis for implantation in a lumen consisting of a tubular wall produced from sheet metal and showing an inner (3) and an outer surface (2), which tubular wall is provided with cuts forming solid struts (1) having a predetermined thickness (T) and enabling the prosthesis to expand, said solid struts (1) having a longitudinal direction (A) and showing reservoirs (4) made in said outer surface (2) for containing a therapeutic agent, characterised in that at least a number of said reservoirs (4) are formed by perforating holes (4) which extend through the solid strut (1) forming in the outer surface (2) of the tubular wall an outer opening (5) and in the inner surface (3) of the tubular wall an inner opening (6), said outer opening (5) having a width (w) measured perpendicular to said longitudinal direction (A) and a length (I) measured in said longitudinal direction (A) which is substantially equal to said width (w), the prosthesis, including said perforating holes (4), being polished electrochemically so that said cuts have a smooth electrochemically polished surface."

VI. In addition to D1 and D11 the following document also played a role for the present decision:

D14: Antithrombotic Therapy After Coronary Stenting, American Heart Journal 138(4):663-669, 1999.

VII. The appellant's arguments brought forward in the written proceedings and relevant for the present decision can be summarised as follows:

Main request - Novelty and inventive step

D1 related to a stent with a tubular wall. However, it did not disclose that this tubular wall was produced from a sheet of metal. Nor did this document disclose that the struts were formed by cuts or that they enabled the prosthesis to expand. Moreover, D1 did not teach perforating holes extending through the solid struts, since a porous layer was provided on both the inner and outer surface. In any event, D1 did not disclose that the stent was electrochemically polished. Therefore, the subject-matter of claim 1 was novel.

Even considering that the claimed prosthesis was distinguished from the stent of D1 solely by the electrochemical polishing could not render the subject-matter of claim 1 obvious. In the stent of D1 the base material was surrounded by a porous layer of biocompatible polymer, so that there was no need at all to improve the smoothness of the surface of the base material to increase the biocompatibility. Rather on the contrary, the person skilled in the art was taught away from this treatment, since the base material was advantageously surface-treated to improve the adhesion of the polymer.

Accordingly, the subject-matter of claim 1 of the main request involved an inventive step.

Auxiliary requests

The auxiliary requests corresponded to those filed at the oral proceedings before the opposition division. They had been filed as a response to a statement of the first examiner during that oral proceedings, according to which claim 1 as granted would not exclude an additional coating.

These requests were based on the disclosure of the application as filed and related to subject-matter which was novel and involved and inventive step.

VIII. The respondent's arguments relevant for the present decision can be summarised as follows:

Main request - Novelty and inventive step

D1 disclosed all the features of claim 1 of the main request. In particular the feature that the stent was electrochemically polished was to be considered as implicitly disclosed, since D1 described the use of a commercially available Gianturco-Roubin stent, which, as evidenced by D14, was electrochemically polished.

In the event that the board considered that D1 did not disclose an electrochemically polished stent, this feature could not justify an inventive step. The performance of this surface treatment to improve the biocompatibility of a stent was standard practice, disclosed for instance in D11. Therefore, it was obvious to apply this treatment. This was true also in the case of the stent of D1 since the porous polymer layer could be made of a bioabsorbable material which left exposed after a while the surface of the base metallic material, whose biocompatibility could be

improved by electrochemical polishing. Hence, the subject-matter of claim 1 did not involve an inventive step.

Auxiliary requests

The opposition division had correctly exercised its discretionary power when it did not admit the auxiliary requests into the proceedings. Moreover, these requests could not be regarded as a reaction to the discussion at the oral proceedings before the opposition division, since D1 and D11 had already been filed together with the notice of opposition, which detailed why D1 disclosed all the features of claim 1 as granted. Therefore, these requests should be disregarded.

Reasons for the Decision

1. The appeal is admissible.

2. Main request - Novelty

2.1 D1 relates to a vascular stent that provides a controlled release of at least one bioactive material into the vascular system, in which the stent is positioned (see column 3, lines 22 to 27). Hence, it discloses a radially expandable prosthesis for implantation in a lumen (see also claim 1 and column 8, lines 25 to 28). The stent of D1 can be obtained by coiling a metal element, for instance shown in Figure 7 to obtain a tubular form (see column 19, lines 16 to 18 column 9, lines 6 to 24). As depicted in Figures 7, 8 and 9 the stent shows an inner and an outer surface

and the tubular wall is provided with solid struts which have a predetermined thickness.

According to column 19, lines 16 to 18 Figure 7 shows the stent in its "flat or planar state". Moreover, Figures 6A, 6B and 9 to 10D, depicting cross sections of the stent, clearly show that the elements of the stent are flat end exhibit sharp angles. Hence, it is clear that the tubular wall is produced from a metal sheet wherein the struts are formed by cuts.

Moreover, the stent of D1 can expand (see also column 8, lines 21 to 31). This expansion is the result of the whole structure of the stent, including the struts. Therefore, it can be considered that the struts enable the prosthesis to expand.

Furthermore, as depicted in Figures 8 and 9 the solid struts have a longitudinal direction and show reservoirs made in the outer surface (28) of the tubular wall for containing a therapeutic agent (18). As clearly shown in Figures 8 and 9 the reservoirs are formed by perforating holes which extend through the solid strut. The perforating holes form in the outer surface of the tubular wall an outer opening (although not in the surface of the polymer 20 which covers the tubular wall) and in the inner surface of the tubular wall an inner opening, said outer opening having a width measured perpendicular to said longitudinal direction and a length measured in said longitudinal direction which is substantially equal to said width.

2.2 However, D1, which is silent on the quality of the surface of the metal, does not mention the performance of electrochemically polishing.

It is true that the structure of the stent is configured as a vascular stent such as the commercially available Gianturco-Roubin FLEX-STENT (see column 8, lines 21 to 24) and that D14, relating to a study of antithrombotic therapy after coronary stenting discloses that a scanning electron microscopic analysis of the Palmatz-Schatz, Gianturco-Roubin, and Micro stents of the first generation used in the study revealed surface irregularities from different electrochemical end polishing procedures (see first page, third paragraph). However, there is no evidence that the FLEX-STENT mentioned in D1 is the same as the Gianturco-Roubin stent analysed in the study of D14. Moreover, D14 does not clearly and unambiguously disclose that the latter had been electrochemically polished.

Accordingly, D1 does not disclose that the prosthesis, including the perforating holes, is polished electrochemically so that the cuts have a smooth electrochemically polished surface.

Therefore, the subject-matter of claim 1 is novel.

3. Main request - Inventive step

3.1 Starting from D1 the object underlying the claimed invention and achieved by the electrochemical polishing is the provision of a prosthesis with increased biocompatibility (see paragraphs [0008] and [0010] of the patent in suit).

3.2 The use of electrochemical polishing for improving the biocompatibility of a stent is common practice in the art. For instance D11 discloses, on page 9, lines 16 to 25, that electrochemical polishing of a stent results

in a smoother surface, thereby reducing the risk of thrombosis and the resistance to blood flow, thus making the stent more biocompatible.

It is true that in the stent described in D1 the base material is surrounded by a porous layer (20) of biocompatible polymer. However, this polymer material can be the same material which is used for the optional additional coating layer 16 (see column 13, lines 20 to 27), which is preferably made of a bioabsorbable polymer (see column 14, lines 19 to 27). Hence, D1 discloses the possibility of realising the porous polymer layer of a bioabsorbable material, so that, after a certain time, the surface of the base material would be exposed. Therefore, contrary to the appellant's view, there is a reason to improve the smoothness of the surface of the base material to increase its biocompatibility.

The appellant pointed out that D1 discloses as advantageous to surface-process the base material in order to promote the adhesion of the porous layer of bioactive material on the base material (see column 17, lines 38 to 42). However, this disclosure does not lead away from electrochemical polishing. First, this advantageous surface treatment is not a compulsory but merely a preferred step of the production process described in D1. Moreover and most importantly, it can be realised by a variety of procedures, including cleaning, physical modifications and chemical modifications (see column 17, line 53 to column 18 line 1) so that it is not incompatible with the performance of electrochemical polishing. Accordingly, the teaching of D1 is not at odds with an electrochemical polishing of the stent.

3.3 Therefore, it was obvious starting from D1 to improve the biocompatibility of the stent by electrochemically polishing it. Hence, the subject-matter of claim 1 of the main request does not involve an inventive step.

4. Auxiliary requests

The auxiliary requests correspond to those submitted during the oral proceedings before the opposition division and not admitted into the proceedings by the opposition division making use of its discretionary power under Article 114(2) EPC (see point 18 of the decision under appeal).

A Board of Appeal should only overrule the way in which a department of first instance has exercised its discretion if the Board concludes it has done so according to the wrong principles, or without taking into account the right principles, or in an unreasonable way.

The opposition division was of the view that the independent claims of all auxiliary requests had not been limited by a mere addition into the independent claim of features already present in dependent claims as granted, but in a way which would have disadvantaged the opponent if they were admitted at the very late stage at which they were filed. Moreover, the opposition division considered that the auxiliary requests were prima facie not allowable. Accordingly, the opposition division has exercised its discretion on the basis of the right principles and in a reasonable way.

The appellant argued that the auxiliary requests had been filed at the oral proceedings as a response to a

statement of the first examiner that claim 1 as granted would not exclude an additional coating. However, the argument that the stent of D1, despite its additional coating, was in accordance with claim 1 as granted had already been submitted in the notice of opposition, filed on 2 August 2006. Therefore, there is no valid reason for the submission of requests which purportedly address this issue for the first time at the oral proceedings on 10 May 2012.

Under these circumstances the board saw no reason to overrule the decision of the opposition division and did not admit the auxiliary requests into the proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare T. Kriner

Decision electronically authenticated