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Datasheet for the decision of 22 September 2011

Case Number: T 0419/08 - 3.2.08

Application Number: 01925368.1

Publication Number: 1261297

IPC: A61F 2/06

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(c), 111(1)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Added subject-matter (no)"
"Remittal (yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0419/08 - 3.2.08

D E C I S I O N
of the Technical Board of Appeal 3.2.08
of 22 September 2011

Appellant: (Patent Proprietor)
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Respondent: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 11 January 2008 revoking European patent No. 1261297 pursuant to Article 101(3)(b) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: M. Alvazzi Delfrate
E. Dufrasne

Summary of Facts and Submissions

I. By decision posted on 11 January 2008 the opposition division revoked European patent No. 1 261 297 on the basis of the ground of opposition under Article 100(c) EPC. The grounds for opposition under Articles 100(a) and 100(b) EPC, which had also been raised in the notice of opposition, were not decided upon.

II. The appellant (patent proprietor) lodged an appeal against this decision on 25 February 2008, paying the appeal fee on the same day. The statement setting out the grounds for appeal was filed on 14 May 2008.

III. In a communication dated 31 January 2011 annexed to the summons to oral proceedings, the board indicated that, if the grounds of opposition under Articles 100(a) and 100(b) EPC needed to be considered, it intended to remit the case to the department of first instance.

IV. Oral proceedings before the board of appeal were held on 22 September 2011.

V. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of auxiliary request 1 filed with letter dated 14 May 2008.

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

VI. Claim 1 of the patent as granted 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 (l) 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."

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

Amendments to claim 1

The feature of claim 1 according to which the prosthesis, including the perforating holes, is polished electrochemically so that the cuts have a smooth electrochemically polished surface, was not disclosed in the application as originally filed.

It was true that the description as originally filed mentioned on page 46, lines 4-13 the possibility of making the perforating holes together with the cuts. However, the following sentence pointed out that the perforating holes could also be made by other techniques. Therefore, the statement on page 46, lines 14-15 that after conventional electrochemical polishing the stents were dipped in a polymer solution did not clearly and unambiguously disclose that the polishing was performed on the stents after making the holes.

Moreover, claim 1 could be construed to mean not merely that the perforating holes were present during the electrochemical polishing but also that the holes had to be electrochemically polished so that the effect of this treatment was detectable on their surface. However, no mention of a detectable effect of the electrochemical polishing on the surface of the penetrating holes could be found in the application as filed.

Furthermore, the application as filed did not disclose that the electrochemical polishing, in particular the conventional electrochemical polishing mentioned on page 46 of the originally filed description, resulted in a smooth surface of the cuts. On the contrary, according to the sentence bridging pages 22 and 23 of the description rough surfaces could appear during polishing.

Finally, even assuming, for the sake of argument, that the passage on page 46 of the original description disclosed the feature according to which the

prosthesis, including the perforating holes, was polished electrochemically so that the cuts have a smooth electrochemically polished surface, the amendment introducing this feature would not be allowable. Since said passage did not mention any ratio of the length and width of the holes, the electrochemical polishing could have been applied to a stent with holes having a length and a width which were not in accordance with present claim 1. Accordingly, the application as filed also failed to disclose electrochemical polishing of a stent which comprised perforating holes forming in the outer surface of the tubular wall an outer opening with a length and a width which were substantially equal.

Therefore, claim 1 had been amended contrary to Article 100(c) EPC.

Amendments to the description (paragraph [0010])

It was not disputed that the application as originally filed disclosed the feature that the length of the holes was substantially equal to the width thereof. However, the application did not disclose that this feature was associated with the effect that more holes could be provided in the outer surface of the prosthesis, i.e. at shorter mutual distances, so that a more homogenous drug delivery was possible, as stated in the first sentence of paragraph [0010] of the patent in suit. The effect above was rather achieved, according to the passage at page 6, lines 23-26 of the originally filed description, by a length of the holes which comprised at the most five times the width thereof.

Nor did the application as originally filed disclose that electrochemically polishing the prosthesis increased its biocompatibility, as stated in the last sentence of paragraph [0010]. It was true that the description mentioned an improvement of the biocompatibility as an aim of the invention, but never specifically associated it with the treatment of electrochemical polishing.

Accordingly, also paragraph [0010] of the description had been amended contrary to Article 100(c) EPC.

Remittal of the case

The decision of the opposition division was completely silent on the grounds of Articles 100(a) and 100(b) EPC. Moreover, the request of the appellant that the board decide the case in full had been made only at a very late stage, namely with letter dated 15 September 2011. Therefore, in the event that the board came to the conclusion that the patent could not be revoked on the basis of Article 100(c) EPC, the case should be remitted to the department of first instance.

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

Amendments to claim 1

The description as originally filed disclosed on page 46, lines 14-15 that after conventional electrochemical polishing the stents were dipped in a polymer solution. This passage clearly referred to

stents having perforating holes previously disclosed on the same page 46, lines 4-13, since the polymer solution was meant to fill the holes.

Moreover, it was clear to the person skilled in the art that the electrochemical polishing was meant to result in a smooth surface, as shown for instance in Figures 4 and 5 of the application. The application also provided sufficient teaching as to how to achieve this effect.

As to the surface of the holes, present claim 1 did not mention any effect of electrochemically polishing it. Therefore, it was immaterial whether or not the possibility of detecting said effect was disclosed in the application.

Hence, the application as originally filed clearly disclosed on page 46 the feature according to which the prosthesis, including the perforating holes, was polished electrochemically so that the cuts have a smooth electrochemically polished surface.

Since the passage at page 46 did not refer to any particular length or width of the holes, it was clear that this disclosure applied also to holes whose width and length were substantially the same, which were disclosed in claim 17 of the application as originally filed.

Accordingly, the amendments to claim 1 did not introduce any subject-matter which extended beyond the content of the application as filed.

Amendments to the description (paragraph [0010])

The application as originally filed disclosed holes whose length was substantially equal to the width, as a preferred case of holes with a length of at the most five times the width thereof. Since according to the passage on page 6, lines 23-26 the latter holes achieved the effect that more holes could be provided in the outer surface of the prosthesis, i.e. at shorter mutual distances, so that a more homogenous drug delivery was possible, it was clear that the same effect could be achieved by holes with essentially the same length and width, as stated in paragraph [0010] of the patent.

Furthermore, the application as originally filed did not only disclose that an improved biocompatibility was the object of the invention, but also described, on page 12, line 28 to page 13, line 4 and on page 13, lines 23 to 25, the link between said object and electrochemical polishing. Therefore, it disclosed that electrochemically polishing the prosthesis increased its biocompatibility, in accordance with the last sentence of paragraph [0010] of the patent in suit.

Therefore, also paragraph [0010] of the description had been amended in accordance with Article 100(c) EPC.

Remittal of the case

Although the appealed decision did not deal with sufficiency of disclosure, novelty and inventive step, the opposition division had already given its view on these issues in the summons to the oral proceedings.

Moreover, there was no absolute right to have an issue decided by two instances and the proceedings concerning the patent in suit and its underlying application had been pending for a considerable time.

Therefore the case should be decided in full by the board of appeal, considering also the issues of sufficiency of disclosure, novelty and inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. Article 100(c) EPC

2.1 During examination proceedings claim 1 was amended to state that the prosthesis, including the perforating holes, is polished electrochemically so that the cuts have a smooth electrochemically polished surface.

Contrary to the respondent's view this wording cannot be construed to require that also the surface of the perforating holes has to be electrochemically polished and that the effect of this treatment is detectable on the surface of the holes. The claim is completely silent on a treatment of the surface of the holes, let alone on a result of this treatment on said surface. Hence, the person skilled in the art would understand that the feature at issue means that the prosthesis, with the perforating holes already formed in it, is subjected to a treatment of electrochemically polishing resulting in a smooth electrochemically polished surface of the cuts.

The description as originally filed discloses on page 46, lines 4-13 that perforating holes are made in a stent. Subsequently it states, on page 46, lines 14-15, that "after conventional electrochemical polishing the stents were dipped in a polymer solution in which the drug was dissolved". Since this sentence follows the description of the formation of the perforating holes in the stents and refers to "the" stents, it is clear that the stents which are polished are those in which perforating holes have already been formed as previously described on page 46, lines 4-13. This is also the sole reasonable technical interpretation, as the polymer solution is intended to be loaded in the perforating holes. Accordingly, the originally filed description clearly discloses, contrary to the respondent's view, that the prosthesis has been subjected to a treatment of electrochemically polishing, after having the perforating holes formed in it.

The respondent submitted that the application as filed did not disclose that electrochemical polishing resulted in a smooth electrochemically polished surface of the cuts. This view cannot be shared, since the very purpose of any polishing treatment is to render a surface smooth. This applies also to the electrochemical polishing described in the application as filed (see for instance Figures 4 and 5). It is true that according to the sentence bridging pages 22 and 23 of the description a specific polishing treatment did not result in a smooth surface. However, this indicates merely a wrong selection of the treatment conditions for that specific treatment, which does not result in

smoothening the surface, i.e. in a successful polishing. Nothing in the application as filed would have led the person skilled in the art to think that the electrochemical polishing is performed for a purpose which does not involve rendering the surface smooth. Hence, the application as originally filed discloses that the prosthesis, including the perforating holes, is polished electrochemically so that the cuts have a smooth electrochemically polished surface.

It is also true, as pointed out by the respondent, that the passage on page 46, lines 4-13 does not mention the ratio of the width and the length of the holes. However, this means that the treatment of electrochemically polishing disclosed on page 46, lines 14-15 can be applied to a stent comprising perforating holes having any of the width-to-length ratios disclosed in the application, for instance those whose width and length are substantially equal (see for instance page 48, lines 20-22 or claim 17). Therefore, the application unambiguously discloses that the prosthesis, including perforating holes which form in the outer surface of the tubular wall an outer opening having a length which is substantially equal to the width, is polished electrochemically so that the cuts have a smooth electrochemically polished surface, in accordance with present claim 1.

2.2 The description as originally filed discloses that the feature according to which the length of the holes comprises at the most five times the width thereof is associated with the effect that more holes can be provided in the outer surface of the prosthesis, i.e.

at shorter mutual distances, so that a more homogenous drug delivery is possible (see page 6, lines 23-26). Hence, it points out that this effect can be achieved for all the holes having a length in the range of at the most five times the width thereof, and in particular for the preferred values in said range. Holes with a length substantially equal to their width are mentioned as a preferred embodiment of the holes having a length in the range of at the most five times the width thereof (see page 48, lines 20-22 or claims 16-17). Hence, the application as originally filed discloses that when the length of the holes is substantially equal to the width thereof, more holes can be provided in the outer surface of the prosthesis, i.e. at shorter mutual distances, so that a more homogenous drug delivery is possible, in accordance with the first sentence of paragraph [0010] of the patent in suit.

2.3 Furthermore, the application as originally filed discloses that the general object of the invention is an improvement in biocompatibility (see page 3, lines 12-15, and page 4, lines 8-12 and lines 23-26). This is achieved inter alia by optimising the surface characteristics by electrochemical polishing (see page 12, line 28 to page 13, line 4 and page 13, lines 23-25). Therefore, contrary to the respondent's view, the application as originally filed discloses that electrochemically polishing the prosthesis increases the biocompatibility, as recited in the last sentence of paragraph [0010] of the patent in suit.

3. Remittal

Under Article 111(1) EPC the board of appeal has discretion to either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution. Since the purpose of appeal proceedings is mainly to review decisions of the first-instance departments, remittal is normally considered in cases where the opposition division issues a decision solely upon particular issues and leaves other substantive issues undecided.

In the present case the decision under appeal dealt solely with the issue of added subject-matter, leaving undecided the issues of sufficiency of disclosure (Article 100(b) EPC) and novelty and inventive step (Article 100(a) EPC). The provisional opinion issued by the opposition division together with the summons to oral proceedings and mentioned by the appellant cannot be considered as a decision.

It is true, as submitted by the appellant, that there is no absolute right to have an issue decided by two instances and that the proceedings concerning the patent in suit and its underlying application have been pending for a considerable time. However, in the present case a decision of the case in full would involve considering legal grounds on which the decision under appeal is completely silent and which are unrelated to the sole legal ground decided upon by the department of first instance.

Moreover, the appellant's request that the board decide the case in full was filed only one week in advance of the oral proceedings, namely with letter dated 15 September 2011, despite the fact that the board had already indicated in the communication dated 31 January 2011 that it did not intend to decide on the objections under Articles 100(a) and 100(b) EPC. Agreeing to this request would thus place the respondent, which had a limited time to prepare itself for a possible debate on said objections, in an unfair position.

Under these circumstances the board finds it appropriate to remit the case to the department of first instance for further prosecution.

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 for further prosecution.

The Registrar: The Chairman:

V. Commare T. Kriner