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**Datasheet for the decision
of 18 September 2012**

Case Number: T 0646/10 - 3.2.08

Application Number: 00991735.2

Publication Number: 1227772

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:

Micro structure stent configurations

Patentee:

Boston Scientific Limited

Opponent:

IPMED GmbH

Headword:

-

Relevant legal provisions:

EPC Art. 114(2), 54, 56

RPBA Art. 12(4), 13(1)

Keyword:

"Admissibility of late-filed documents - partly"

"Novelty - yes"

"Inventive step - yes"

Decisions cited:

-

Catchword:

-



Case Number: T 0646/10 - 3.2.08

DECISION
of the Technical Board of Appeal 3.2.08
of 18 September 2012

Appellant: IPMED GmbH
(Opponent) Am Rathausplatz
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Representative: Trinks, Ole
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Respondent: Boston Scientific Limited
(Patent Proprietor) The Corporate Centre
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Representative: Peterreins, Frank
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 15 January 2010
rejecting the opposition filed against European
patent No. 122772 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman: T. Kriner
Members: R. Ries
A. Pignatelli

Summary of Facts and Submissions

- I. By its decision posted on 15 January 2010 the opposition division rejected the opposition against European patent No. 1 227 772.
- II. On 19 March 2010, the appellant (opponent) lodged an appeal against this decision, paying the appeal fee on the same date.

The statement setting out the grounds of appeal was received on 25 May 2010. Enclosed therewith, the appellant submitted for the first time additional documents D16 to D46.

- III. In an official communication of 13 March 2012 annexed to the summons to oral proceedings, the Board gave its provisional view on the case. Particular reference was made to Article 114(2) EPC, according to which the European Patent Office may disregard facts and evidence which were not submitted in due time by the parties, and also to Article 12(4) of the Rules of Procedure of the Boards of Appeal (RPBA), according to which it is within the Board's discretion to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first instance proceedings.

In its response dated 6 June 2012 to the official communication, the appellant enclosed a further document (D47), which in its view was highly relevant to the claimed subject matter.

IV. Oral proceedings took place before the Board on 18 September 2012. The following requests were made:

The appellant requested that:

- the decision under appeal be set aside and the patent be revoked;
- documents D16 to D47 be admitted into the proceedings; and
- document D12(2), not admitted by the opposition division since it was late-filed, post-published and held irrelevant, should be considered on appeal.

The respondent (patent proprietor) requested that:

- the appeal be dismissed and the patent be maintained as granted (main request); or that
- the patent be maintained in amended form on the basis of the auxiliary requests I to VI filed on 20 August 2009;
- documents D12(2) and D16 to D47 be rejected as late-filed.

V. Independent claim 1 as granted reads as follows:

"1. A stent comprised of a plurality of interconnected struts arranged with respect to each other to provide a micro structure having the following dimensions:

Strut width 6.4 - 51 μm

Maximum pin opening 51 - 510 μm ,

wherein the maximum pin opening is defined as the largest diameter of a pin which can be passed through the cell opening,

- said stent is of a closed cylindrical construction in which expansion is accompanied by a deformation of the strut structure, and
- said struts have - after expansion - a strut thickness of about 6.4 - 100 µm such that said micro structure facilitates support with minimal disruption."

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

- D12(2): Handbook of Coronary Stents, third edition 2000, edited by P. W. Serruys, and M. JB Kutryk, published by M. Dunitz Ltd, 2000, pages 41 to 44, 47;
- D16: Handbook of Coronary Stents, 2nd edition 1998, edited by P. W. Serruys, and M. JB Kutryk, published by M. Dunitz Ltd, 1998 pages 203 to 212;
- D17(a): Invoice No. 608850 dated 22 January 1999 and delivery note;
- D17(b): Invoice No. 608851 dated 22 January 1999 and delivery note;
- D17(c): Invoice No. 608955 dated 04 February 1999 and sales order acknowledgement;
- D18: Interventional Vascular Product Guide, Martin Dunitz, published 1999, pages 155, 156.

VII. The appellant's arguments are summarized as follows:

The opposition division did not exercise its discretion correctly when it did not admit D12(2) into the proceedings. In fact, the main arguments of the appellants in the opposition proceedings were based on the BiodivYsio PC stent, which according to D12(2) was launched in August 1998. This stent was also described in document D16, which was the pre-published 2nd edition of document D12(2) (3rd edition). However, in its decision, the opposition division focused on the public prior use of the "BiodivYsioTM SV Small vessel PC" stent, which was also described in the post-published document D12(2) and decided that the link between the two stents was not clearly established. The decision was therefore based on the wrong object.

In support of the appellant's interpretation of the term "launched" in D12(2) and D16, which the opposition division doubted meant "sold on the market", invoices and delivery certificates were submitted on appeal (D17(a) to (c)) to prove that the "BiodivYsio" stent 11 mm (product code 580-110601) and 15 mm (product code 580-150601) were sold before the priority date. According to the appellant, documents D17(a) to (c) showed that DivYsio stents CL (CL = closed design) having a length of 11 mm and 15 mm were sold in January and February 1999, respectively. Document D18 was submitted to establish the link between the stent described in D12(2) and the sold stents. In fact, the product codes 580-110601 and 580-150601 in D17(a) to (c) complied with the codes given in document D18 which identified the stents as "BiodivYsioTMPC-coated stent".

D12(2) disclosed on page 42 a BiodivYsio PC stent, 11 and 15 mm long, 50 μ m to 80 μ m wide and 90 μ m thick, which could be expanded to diameters ranging from 2.0 to 4.0 mm (11, 15 & 18 mm). A 15 mm "closed" design, having an additional longitudinal member within the open space to confer extra support was depicted in D12(2), Figure 5.1 and page 47, "Indications for use". Such a stent was also disclosed in Figures 20.1, 20.3 and page 204 of the pre-published version D16. Both documents disclosed that the stent had six elements (cells) in the circumferential direction, which elements were divided by reinforcing longitudinal members to form 12 cells.

The abbreviation "CL" in D17(a) to (c) meant "closed design". The same product codes and the technical specifications of the "BiodivYsioTM PC-coated stent were found in the pre-published documents D18 and D20. Documents D19 and D20 proved that the "BiodivYsio stent was provided "for 2.0 to 4 mm indication only". Since the opposition division had not exercised its discretion correctly, it was therefore requested that the rejected document D12(2) as well as documents D16 to 20 enclosed with the grounds of appeal be admitted into the proceedings.

Document D47 was enclosed with the appellant's response to the Board's official communication annexed to the summons to oral proceedings. The appellant argued that the claimed subject matter, in particular "the pin-opening" parameter was unusual in the art and could not be searched in the available databases. Therefore, this document could not have been submitted earlier. D47 was found by chance and was novelty-destroying for the

subject-matter of claim 1 of the patent at issue. The appellant further argued that D47 had been known to the respondent-patentee at least since 2001 given that the respondent filed an opposition against the patent based on D47. Hence the introduction of D47 could by no means be surprising for the respondent.

Concerning novelty, the strut width and strut thickness of the BiodivYsio PC stent were within the claimed ranges. Based on these data and an expansion diameter of 2.0 mm and 12 cells for the "closed design" BiodivYsio PC stent, as was explained in detail in the appellant's letter dated 25 May 2010, pages 12 and 13, the maximum PIN opening was calculated to be 470 μm , which met the claimed range of 51 to 510 μm . Hence the known stent sold according to D17(b) and (c) anticipated the stent claimed in the patent at issue. The subject-matter of claim 1 as granted therefore lacked novelty.

In the event that novelty was accepted on the basis that the maximum PIN opening was considered as not explicitly described in the prior art, the appellant argued that no technical problem was solved by the feature of the "maximum PIN opening" since it was an arbitrarily selected parameter. Consequently, an inventive step could not be based on this feature.

No technical effect was associated with selecting the micro-structural dimensions of the claimed stent. More specifically, no technical problem was solved by choosing a maximum PIN opening in the range of 51 to 510 μm , which was selected merely arbitrarily rather

than on purpose. Consequently, this feature could not justify an inventive step over the prior art.

In a second line of argument, the appellant expressed the view that selecting a maximum PIN opening in the range of 51 to 510 μm would have been obvious to the skilled person.

VIII. The respondent's arguments are summarized as follows:

On appeal, the appellant filed 30 new documents and based at least four new attacks upon them. It raised issues which the opposition division had never looked at. No justification was provided as to why documents D16 to D47 could not have been filed at an earlier stage. None of the documents was more relevant than the documents which were admitted by the opposition division. Therefore neither post-published document D12(2), which was correctly rejected by the opposition division, nor late-filed documents D16 to D47 should be admitted into the proceedings.

While D12(2) described the BiodivYsio PC stent, document D16 referred to the DivYio stent. In fact, no proof existed to show that both stents actually had the same design. Moreover, D16 stated that the 15 mm "closed" design with a longitudinal member and a 28 mm "open version" without such a supporting member existed and that both stents had only six elements in circumferential direction for use in vessels between 3.0 and 4.0 mm diameter, as document D18 stated likewise. This was contrary to the appellant's assumptions based on the use of a strut width of 50 μm , 12 cells and a 2 mm diameter for calculating the

maximum PIN opening. Given these uncertainties and contradictory technical information, there was no basis to conclude that the stents sold according to D17(a) to (c) actually satisfied the micro-structural criteria of the stent claimed in the patent. The claimed stent was therefore novel over the cited prior art.

As to inventive step and the problem solved by the claimed stent, reference was made to the patent specification, paragraph [0006] which reflected that the openings in the stent wall were so small and its micro-structure so fine so that the stent was considered by the body as non-existing, i.e. "invisible" to the body and to the body constituents. Therefore, the stent design was selected on purpose, contrary to the appellant's allegations. The subject matter of claim 1 therefore also involved an inventive step.

Reasons for the Decision

1. The appeal is admissible.
2. Admissibility of the late-filed documents
 - 2.1 The Board has the power to review the way in which the first instance exercised its discretionary power if the appellant contests it. In the present case, the appellant contests the exercise of the discretionary power by the opposition division concerning the refusal to admit D12(2) into the proceedings.

2.2 According to the opposition division, D12(2) indicated that only the BiodivYsioTM Small Vessel (SV) PC stent had been launched in August 1999. Furthermore, in the opposition division's view, the term "to launch a stent" did not necessarily mean that the stent was actually sold and thus was available to the public. Moreover it was held that the link between the BiodivYsioTM Small Vessel PC stent and the BiodivYsioTM stent was not clearly established and that the drawing 5.3 of D12(2), again not clearly defined as BiodivYsioTM Small Vessel PC stent, only referred to an "open design" stent rather than to a "closed design" stent. Given that document D12(2) was published in 2000, i.e. after the priority date of the patent of 9 November 1999, and was not considered relevant, it was not admitted by the opposition division.

2.3 The appellant's arguments were, however, based on the BiodivYsio PC stent. It thus appears that they were misunderstood by the opposition division, which in its decision focused on the BiodivYsio Small Vessel PC stent and did not discuss the BiodivYsio PC stent. In such a situation the opposition division did not exercise its discretion correctly and document D12(2) is to be admitted into the proceedings.

2.4 Documents D16 to D46 were filed for the first time with the grounds of appeal.

According to Article 12(4) RPBA, the Board has the power to hold inadmissible documents filed for the first time with the statement setting out the grounds of appeal if they could have been presented in the first instance proceedings.

2.5 As the appellant contests the interpretation of the term "launched" given by the opposition division in its decision, it had to prove that this interpretation was wrong and that "launched" did mean "sold". The submission of documents for this purpose has to be considered as a reaction to the decision. In fact, documents D16, D17(a) to (c) and D18 clarify the circumstances of the prior use and the interpretation of the term "launched" in D12(2) since they prove that the stents were sold in 1998 and that they had the features described in D12(2).

Given this situation, the Board admitted documents D16, D17(a) to (c) and D18 into the appeal proceedings.

2.6 As far as documents D19 to D46 are concerned, the Board holds that they are not related to the opposition division's interpretation of the term "launched". No other reasons were given for their late filing. As to the issue of novelty and inventive step of the claimed stent, the appellant submitted several lines of argument based on these documents - arguments that were unknown to, and therefore not dealt with by the opposition division - without explaining why it could not have argued thus in the first instance proceedings. Put another way, the appellant has created a completely fresh case on the basis of new prior art, raising issues never considered by the opposition division. The appeal thus goes far beyond the factual and legal framework on which the impugned decision of the opposition was based.

Admitting these documents would have resulted either in the remittal of the case to the first instance for further prosecution, or in the assessment of newly submitted facts and evidence for the first time on appeal. In fact, remitting the case to the first instance would have resulted in the appellant being permitted to have "a second round of opposition proceedings", which is contrary to the criterion of procedural economy.

Given this situation, the Board decided not to admit documents D19 to D46 into the appeal proceedings.

2.7 D47 was filed after the filing of the statement of grounds. According to Article 13(1) RPBA, the admission of such a submission is at the Board's discretion. The criteria for the exercise of this discretion are inter alia the complexity of the new subject-matter, the state of the proceedings and procedural economy.

2.8 The appellant's arguments to justify the late filing of document D47 are not convincing.

It frequently happens that a party is confronted in patents with "unusual parameters" which are used in order to describe a specific property of a product or a process step. Moreover, if document D47 was known to the respondent, as alleged by the appellant, the Board's is unable to understand why this document was unknown to the appellant which - like the respondent - is skilled in the art and therefore an expert in stent technology. Consequently, none of the appellant's arguments can excuse the late filing of document D47. Since a new case would arise if the document was

admitted, so that a remittal would be necessary, the admission of this document would go against procedural economy. Under these circumstances, the Board finds that the submission of document D47 at a very late stage of the proceedings should not be accepted.

3. Public prior use; novelty

- 3.1 Document D12(2) discloses on page 41, "History", that the BiodivYsio PC stent (penchant premounted PC stent) was launched in August 1998. Figure 5.1 shows such a stent, 15 mm long, closed design (a) as manufactured and (b) after expansion. In contrast to the "open design" (D12(2), Figure 5.3), the "closed design" stent has a longitudinal strut in the space formed by the arrow heads. This is confirmed on page 47 of D12(2):
- "Indications for use": *"At present, there are two basic designs available: an extra support design which has a longitudinal member within the open space of each arrowhead (Figure 5.1) to confer greater support, and an open version which has greater flexibility and potential for side branch access (Figure 5.4). There are six elements circumferentially for use in vessels between 2.0 and 4.0 mm."* Moreover, according to the technical specifications given in the Table on page 42 of D12(2), (strut dimensions), the BiodivYsio PC stent comprises struts which are 0.05 to 0.08 mm wide and 0.09 mm thick. The expansion range of the BiodivYsio PC stent is described to be between 2.0 and 4.0 mm for the 11, 15 & 18 mm length. The invoices and proof of delivery D17(b) and (c) in combination with D18 vouch for the sale and public availability of the BiodivYsio PC stent (product codes 580-1100601 and 580-150601) before the priority date of the impugned patent. It

seems plausible that the abbreviation "CL" featuring in D17(b) and (c) means "closed" design, as alleged by the appellant.

Based on the data given in D12(2), D17(a) to (c) and D18 and assuming an expansion range of 2.0 mm and $2 \times 6 = 12$ cells due to the reinforcing longitudinal member for extra support in the "closed design", the appellant calculated for the BiodivYsio PC stent a maximum PIN opening of 470 μm , which falls within the claimed range. In the appellant's view, this proved that the public prior use of the BiodivYsio PC stent takes away the novelty of the subject matter of the claims as granted.

- 3.2 For the following reasons, the Board holds that it has not been proved that the sold stents had an expansion range of 2.0 to 4.0 mm. In fact, this expansion range is disclosed in the post-published document D12(2) on page 42. However, on page 155 of the pre-published document D18 an expansion range of 3 to 4 mm is indicated for the stents indicated by the product codes 580-110601 and 580-150601 referred to in D17(b), (c), which are the sold stents. The expansion range of 3.0 to 4.0 mm for the DivYsio stent (BiodivYsio PC stent) is corroborated by the specifications in the Table on page 204 and page 211 of document D16 (which is the pre-published 2nd edition of document D12(2)), disclosing a 15 mm "closed" design stent and an 28 mm "open version". Both stents have six elements (cells) circumferentially, for use in vessels between 3.0 and 4.0 mm in diameter. Since the indication of an expansion range of 2.0 to 4.0 mm is only present in the post-published document and all the pre-published documents indicate an expansion range of 3.0 to 4.0 mm,

it is only proved that the stents which were the object of the prior use had an expansion range of 3.0 and 4.0 mm.

There is also no reliable evidence corroborating the appellant's allegation that the known stent could have been used "out-of-range" with a 2 mm expansion by a physician in emergency situations or, for example, when treating children.

- 3.3 For an expansion diameter of 3.0 mm, however, the maximum PIN opening is 735 μm according to the calculations given on page 13 of the appellant's letter dated 25 May 2010. This value is clearly outside the maximum PIN opening range of 51 to 510 μm for the claimed stent.

Consequently, there is no reliable basis implying that before the priority date of the patent at issue the BiodivYsio PC stent was expanded to 2.0 mm, as assumed in the appellant's calculation. Hence it has not been proven that the known stent satisfied the maximum PIN opening defined for the claimed stent.

The subject-matter of claim 1 as granted is therefore novel over the public prior use.

4. Inventive step

The Board concurs with the appellant's assessment that the public prior use qualifies as representing the closest prior art.

4.1 As set out in paragraph [0006] of the patent specification, the basic idea behind the invention is to provide a stent of fine (micro-) structure that provides adequate vessel support but wherein the openings in the stent are so small that it creates minimal disruption of the vessel surface, and is so fine that it is for all practical purposes "invisible" to the body and to the body constituents such as blood flow. Thus, the dimensions and microstructure of the claimed stent, including the maximum PIN opening, have been selected deliberately rather than by guesswork and the Board is satisfied that they do contribute to solving the technical problem as defined above.

4.2 In a second line of argument, the appellant contended that starting from the public prior use, the selection of a maximum PIN opening in the range of 51 to 510 μm would have been obvious to the skilled person.

However, aside from the unsupported allegation of a possible "out-of-range" use of the BioDivYsio PC stent by a physician in exceptional or emergency situations, which argument has already been dealt with above, no evidence was presented by the appellant in support of its contention.

4.3 Consequently, the subject-matter of claim 1 of the patent as granted involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner