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Datasheet for the decision of 8 December 2010

Case Number: T 1546/08 - 3.2.02

Application Number: 98958475.0

Publication Number: 1028672

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:
Intravascular stent and method for manufacturing an intravascular stent

Patentee:
EXPANDABLE GRAFTS PARTNERSHIP

Opponent:
Boston Scientific Scimed, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 54(1)(2)(3), 56, 83, 84, 114(2), 123(2)
EPC R. 80, 139
RPBA Art. 12(2), 13(1)(3)

Keyword:
"Sufficiency of disclosure (yes)"
"Extended subject-matter (no)"
"Novelty (yes, after amendment - third auxiliary request)"
"Inventive step (yes, after amendment - third auxiliary request)"

Decisions cited:
G 0004/95, T 0487/91, T 1329/04, T 0063/06

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1546/08 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 8 December 2010

Appellant I: (Patent Proprietor)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 22 July 2008 concerning maintenance of European patent No. 1028672 in amended form.

Composition of the Board:

Chairman: M. Noël
Members: C. Körber
J. Geschwind

Summary of Facts and Submissions

I. On 22 July 2008 the Opposition Division posted its interlocutory decision concerning maintenance of European patent No. 1 028 672 in amended form.

II. Appeals were lodged against this decision by both the patentee and the opponent, by notices received on 22 September 2008 and 4 August 2008, respectively, with the appeal fees being paid on the same respective days. The statements setting out the grounds of appeal were received from both parties on 1 December 2008.

III. By communication of 6 October 2010, the Board forwarded its provisional opinion to the parties.

IV. Oral proceedings were held on 8 December 2010.

Appellant I (patentee) requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the set of claims filed as main request with letter of 1 December 2008, or on the basis of the set of claims filed as first auxiliary request with letter of 8 November 2010, or on the basis of the sets of claims filed as second and third auxiliary requests with letter of 1 December 2008 (renumbered according to the letter of 8 November 2010).

Appellant II (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

V. The following documents are of importance for the present decision:

D1: WO-A-9742911
D2: WO-A-9822045
D3: US-A-5192307
D4: US-A-4869714
D5: "New Advances in Endovascular Technology", Texas Heart Inst. J., Vol. 24, No. 3 (1997), p. 156-159
D9: "Quantitative analysis of cell proliferation and orientation on substrata with uniform parallel surface micro-grooves", Biomaterials , Vol. 17 No. 11 (1996), p. 1093-1099
D10: "Review: Effects of Substratum Morphology on Cell Physiology", Biotechnology and Bioengineering, Vol. 43 (1994), p. 764-771
D11: EP-A-0692264.

VI. Independent claims 1 and 23 of the main request read:

"1. An intravascular stent (300) having an outer surface (302) and an inner surface (301), the improvement comprising:

at least one groove (400) disposed in the inner surface (301) of the stent (300), wherein the at least one groove (400) has a width, a length having a dimension greater than the width, and a depth less than the distance between the inner surface and the outer surface of the stent, the at least one groove (400) promoting migration of endothelial cells onto the inner surface (301) of the stent (300) when the stent (300) is implanted."

"23. A method for manufacturing an intravascular stent (300) according to claim 1, the stent (300) having an outer surface (302) and an inner surface (301), comprising:

providing at least one groove (400) in the inner surface (301) of the stent (300), wherein the at least one groove (400) has a width, a length having a dimension greater than the width, and a depth less than the distance between the inner surface and the outer surface of the stent (300), the at least one groove (400) promoting migration of endothelial cells onto the inner surface (301) of the stent (300) when the stent (300) is implanted."

Claims 2 to 22 and 24 to 44 are dependent claims.

Independent claims 1 and 23 of the first auxiliary request comprise the additional feature:

"the width being defined by side walls (303) of the at least one groove (400), the depth being defined by a bottom of the at least one groove (400), wherein the side walls and the bottom are continuous with one another" inserted before the expression "the at least one groove (400) promoting migration ...".

Independent claims 1 and 22 of the second auxiliary request correspond to claims 1 and 23, respectively, of the main request, with the additional feature of the width of the at least one groove being "within a range of 2 to 40 microns" and dependent claims 21 and 43 of the main request being deleted.

Independent claims 1 and 22 of the third auxiliary request correspond to claims 1 and 23, respectively, of the main request, with the additional feature of the depth of the at least one groove being "within a range of one-half to ten microns" and dependent claims 20 and 42 of the main request being deleted.

VII. The arguments of patentee-appellant I are summarised as follows:

Late-filed documents D9, D10 and D11 were not prima facie relevant and should therefore not be admitted into the proceedings. The first auxiliary request should be admitted since it was filed in order to overcome the novelty objection vis-à-vis D2 raised in the Board's communication of 6 October 2010. Mr. J.C. Palmaz, being a co-inventor of the patent in suit, should be allowed to speak as a technical expert during the oral proceedings before the Board.

The amendments introduced into the independent claims as granted were in line with the general understanding of the term "groove" and also clearly derivable from the drawings. The additional features introduced in the second and third auxiliary requests were based on original dependent claims depending directly from the original independent claims and did not represent an unallowable intermediate generalisation.

As explained by Mr. J.C. Palmaz, the edges of a groove affected the otherwise zig-zag type of migration of the endothelial cells on a flat surface so that they were guided by the edges of the groove to follow those edges. Their average migration rate thus became

accelerated along the groove. Since all of the grooves depicted in the drawings of the patent in suit clearly exhibited edges, the disclosure was sufficient with respect to the ability of the grooves to promote migration of endothelial cells. Documents D5 and D9 were not suited to raise any doubts in this respect. There was no reason to shift the burden of proof to the patentee under these circumstances.

D1 merely disclosed recesses of irregular circular-like shape rather than grooves. When fibres were used to produce the recesses, they would overlap in a disordered manner, resulting in an irregular pattern of recesses of variable shapes and depths. Moreover, D1 was silent about the size of the fibres. Furthermore, migration of cells was only disclosed through the traversing passageways of the stent, and not onto its inner surface as presently claimed.

D2 did not disclose grooves having a bottom since, when implanted, the coiled stent would form spaces between successive overlapping layers of the sheet material due to the non-cylindrical shape of the blood vessels and the pulsing of the blood. The overlapping slots or perforations 28 would produce net apertures, and endothelial cell growth was only disclosed to be facilitated through these net apertures and thus through the walls of the stent, rather than onto its inner surface as claimed. The values of the diameter of the net apertures indicated in the first paragraph of page 11 did not make it possible to derive any width dimension of the perforations.

D11 merely taught a stent wall consisting of a microstructure composed of fine fibres which did in no way constitute a "groove" in the sense of the patent in suit.

The inner detent 48 of D3 had the structural function of locking the stent in a fixed expanded state. Its depth almost corresponded to the wall thickness of the stent. When reducing its depth to the range as claimed in the third auxiliary request, the locking function would no longer work. The very slight curvature of the detent had no effect on the migration of endothelial cells.

D4 disclosed a blood vessel prosthesis with an inner surface having cylindrical recesses 16, rather than grooves as claimed. These recesses had the function of anchoring blood components and did not promote endothelial cell migration onto the inner surface. The anchoring would no longer function if the disclosed values of the depth of the recesses were reduced to the range as claimed in the third auxiliary request.

The technical problem to be solved by the patent in suit was to prevent low-flow thrombosis by increasing the rate of migration of endothelial cells onto the inner surface of the stent after implantation. Neither D3 nor D4 gave a hint towards the solution in the form of a groove as claimed.

D10 was entirely irrelevant in that the substratum materials studied would be unsuitable for fabricating stents. Moreover, vascular endothelial cells were not investigated at all. Furthermore, in those studies

where migration was investigated, no results were indicated and the types of cells used were very different from vascular endothelial cells. Accordingly, even when taking into account the teaching of D10, the skilled person starting from D3 or D4 would not arrive in an obvious way at the invention, in particular not as claimed in the third auxiliary request.

VIII. The arguments of the opponent-appellant II are summarised as follows:

D10 and D11 were filed at the earliest possible moment in reaction to the contested decision and should thus be admitted into the proceedings. D9 had been filed even earlier, during the oral proceedings before the Opposition Division, and was also prima facie relevant. The first auxiliary request filed belatedly by the patentee-appellant I was objectionable under Articles 84 and 123(2) and Rule 80 EPC and thus not immediately admissible. Moreover, it could have been filed earlier since the novelty objection vis-à-vis D2 was already raised in the impugned decision. Mr. T. Scheuermann should be allowed to speak as a technical expert, in particular in response to any statements made by Mr. J.C. Palmaz.

The features regarding the width and depth of the groove introduced into the independent claims as granted were not explicitly comprised in the original disclosure. They could also not be extracted in isolation from the drawings. The alternative meanings of the term "groove" indicated at page 7, lines 12 to 14, of the patent application did not suggest that a specific channel with a length greater than its width

was meant. The correction of the reference numeral in claim 28 of the main request was not occasioned by a ground of opposition, thus rendering this request unallowable under Rule 80 EPC. The ranges of width and depth of the groove as introduced in the independent claims of the second and third auxiliary requests, respectively, represented intermediate generalisations which were not allowable under Article 123(2) EPC.

The disclosure of the invention was insufficient in that the specification was entirely silent about how the at least one groove had to be configured in order to achieve the desired effect of promoting migration of endothelial cells onto the inner surface of the stent when the stent was implanted. The expression "It is believed that ..." used in the respective context in the patent (cf. paragraphs [0009] and [0022]) indicated that in fact nothing was disclosed going beyond the mere desire to achieve this effect. According to T 1329/04, it should at least be made plausible by the disclosure that its teaching did indeed solve the problem it purported to solve. Verification of this effect would in fact require in-vivo studies since the independent claims defined it with respect to the stent in the implanted state. This, however, would represent an undue burden on the opponent. In such a situation, the patentee should bear the burden of proof since the opponent had reasonably shown that the claimed effect was at least questionable (T 63/06). This was demonstrated by the fact that one of the inventors, Mr. J.C. Palmaz, had referred to the effect of surface structure on migration as an "unexplored hypothesis" in D5 only 4 days before the priority date of the patent in suit. Moreover, D9 described the effect of grooves

on the migration of cells as a very open and uncertain field and revealed that grooves of a depth of 0.5 microns did not have any effect on cell proliferation. With respect to Mr. Palmaz's explanation of the effect being due to the edges of the grooves as given during the oral proceedings before the Board, there was no indication in the patent disclosure that the edges could be of any relevance in this regard, and the term "edges" was not even mentioned. Moreover, even "rounded indentations", not having any edges, were denoted as "grooves".

D1 was novelty-destroying in respect of the independent claims of the main request since it disclosed that the recesses on the inner surface of the stent could be produced by fibres, the resulting recesses hence being elongate and thus falling under the definition of the grooves as claimed. D1 was also novelty-destroying for the ranges of width and depth according to the second and third auxiliary request, respectively, in view of the dimensions of the recesses disclosed in the second paragraph of page 7, which comprised values falling within the claimed ranges. Moreover, the promotion of cellular migration was explicitly addressed.

D2 was also detrimental to the novelty of the independent claims of all requests as the slots 28 in the innermost layer formed "grooves" as claimed, since it was explicitly disclosed that the layers bear against one another under spring force. Consequently, there were no gaps or spaces between these layers, the non-overlapping portions of the slots thus forming grooves. Their widths fell into the range claimed in the second auxiliary request, in particular when taking

into consideration the values of the diameters of the "net aperture" openings 60 disclosed at the top of page 11 and calculating the corresponding widths therefrom. Moreover, the sheet thickness of 0.0005 inches or less disclosed in line 1 of page 13 anticipated the range of depth claimed in the third auxiliary request. The facilitation of endothelial cell growth was also mentioned explicitly in this document.

The subject-matter of the independent claims of all requests was furthermore anticipated by D11 which disclosed a stent with a microstructure composed of fine fibres forming corresponding grooves. The dimensions of the fibres disclosed in D11 were within the ranges of widths and depths as claimed. Moreover, endothelial cell migration was explicitly addressed.

There was a lack of inventive step in view of D3 or D4 in combination with D10. The independent claims of the third auxiliary request differed from D3 only by the specific range of groove depths claimed. The contested patent, however, was entirely silent about any technical effect to be obtained thereby. Moreover, D10 gave numerous examples of grooves having depths falling in the claimed range and promoting or guiding cell migration. The Ti-coated substrates listed in Table I were comparable to the surfaces of stents made from titanium, which was a well-known material for stents. As could be seen from D11, endothelium was only a special type of epithelium, the latter being a type of cellular tissue specifically studied according to Table I of D10. Moreover, there were many indications in D10 that the surface morphology should be in the same order of magnitude as the size of a cell and that

grooves could enhance cell migration by confining the cells in the grooves.

D4, relating to a blood vessel prosthesis, was an equally suitable starting point since a stent was a special type of prosthesis. In column 1, lines 28 to 35, the promotion of the growth of a surface layer of endothelial cells was specifically addressed. Taking into account the teaching of D10, it was obvious to modify the recesses 16 of D4 into grooves having a depth in the range as claimed in the third auxiliary request.

Reasons for the Decision

1. The appeals are admissible.

2. Late-filed submissions and oral submissions by technical experts

2.1 Documents D9, D10 and D11

Documents D10 and D11 were filed by the opponent-appellant II together with its statement of grounds of appeal. These documents were submitted at the very beginning of the appeal procedure in reaction to the impugned decision and were cited with respect to novelty and inventive step. Their introduction does not result in an unacceptable delay of the appeal procedure. Document D9 was submitted by the opponent already during the oral proceedings held before the Opposition Division, yet disregarded as late-filed under Article 114(2) EPC. Although the Opposition

Division exercised its respective discretion properly, this document is regarded as useful by the Board for assessing the question of sufficiency of disclosure. Accordingly, the Board admits all three documents D9, D10 and D11 into the appeal proceedings in the exercise of its discretion under Article 114(2) EPC.

2.2 First auxiliary request

This request was filed by the patentee-appellant I on 8 November 2010, i.e. about one month before the oral proceedings before the Board and about one month after the Board's communication of 6 October 2010. The argument that it was filed in order to overcome the novelty objection vis-à-vis D2 raised by the Board is not acceptable since D2 was already present in the opposition procedure and the Board's objection only confirmed the position of the Opposition Division. Accordingly, this request could and should have been filed by the patentee-appellant I already with the statement of grounds of appeal (see Article 12(2) RPBA). Moreover, this late-filed request is not clearly allowable as it gives rise to further objections, inter alia under Articles 123(2) and 84 EPC, as explained in the letter of the opponent-appellant II dated 2 December 2010. Accordingly, in the exercise of its discretion under Article 13(1) and (3) RPBA, the Board does not admit this late-filed request.

2.3 Technical experts

In consideration of the criteria set forth in G 4/95 (point 2 of the headnote), the Board exercised its discretion to allow the technical experts offered by

both appellants to make oral submissions on specific issues raised by the Board, under the control of their respective representatives.

3. Amendments

With regard to the basis of the amendments, reference will be made in the following to the published version WO-A1-99/23977 of the application as originally filed.

3.1 Main request

Claims 1 and 23 of the main request comprise the features of original claims 1 and 2, and 24 and 25, respectively, with the following additional features concerning the "at least one groove":

a) its length having a dimension greater than its width;

b) its depth being less than the distance between the inner surface and the outer surface of the stent;

c) the groove promoting migration of endothelial cells onto the inner surface of the stent when the stent is implanted.

Feature a) is implied by the general definition of the term "groove". Moreover it can be directly derived from Figures 8, 15 and 16, each of which depicts a groove 400 having a length greater than its width. The claimed specification of the dimensional relationship according to feature a) is perfectly acceptable without having to incorporate further features relating for example to

the specific forms of the grooves shown in the drawings. The fact that at page 7, lines 13 and 14, it is mentioned that the term "groove" is intended to be construed as a "channel or depression", or, inter alia, a "rounded indentation" or a "mark, having been made with something sharp or jagged" does not alter the understanding of the general definition of the term "groove" as included in claims 1 and 23.

Feature b) is implied by the fact that a "groove" must have a bottom, which, when the groove is present in a stent having an inner and an outer surface, means that its depth is less than the distance between these surfaces. Furthermore, this feature is clearly supported by each of Figures 9 to 16. Like feature a), feature b) can be simply taken from the drawings without having to additionally define specific cross-sectional shapes of the grooves. A claimed combination of features does not have to take over all the features of an illustrated embodiment. Finally, the fact that the depth of the groove may vary along its length, as defined in original claim 4, does not mean that the groove does not have a bottom at all at certain locations.

Feature c) is based on page 10, lines 6 to 11.

3.2 Second auxiliary request

The additional feature of the width of the groove being "within a range of 2 to 40 microns" as included in independent claims 1 and 22 of the second auxiliary request is disclosed as such in original dependent claims 22 and 45 (with the term "approximately" being

deleted). Since these claims depend directly from original independent claims 1 and 24, respectively, this additional feature is disclosed without requiring any further restriction. Its incorporation into the independent claims therefore does not represent an unallowable intermediate generalisation.

3.3 Third auxiliary request

The additional feature of the depth of the groove being "within a range of one-half to ten microns" as included in independent claims 1 and 22 of the third auxiliary request is disclosed as such in original dependent claims 21 and 44 (with the term "approximately" being deleted). Since these claims depend directly from original independent claims 1 and 24, respectively, the incorporation of this feature does not represent an unallowable intermediate generalisation either.

3.4 All requests

In claim 28 of the main request and claim 27 of the second and third auxiliary requests, reference numeral 400 has been replaced by the correct number 410 denoting the longitudinal axis of the groove (see Figure 8 and page 9, line 9 of the application). Although this amendment is not occasioned by a ground for opposition under Rule 80 EPC, it represents an obvious correction of a minor typographical error which does not change the interpretation of the claim and is therefore admitted by the Board under Rule 139 EPC.

It follows that the amendments made to the claims of the main, second and third auxiliary requests do not

comprise added subject-matter in breach of Article 123(2) EPC.

4. Sufficiency of disclosure

It has been contested that the disclosure is entirely silent about how the at least one groove has to be configured in order to promote migration of endothelial cells onto the inner surface of the stent when the stent is implanted, a feature which is present in both independent claims according to all requests. This feature relates to the technical problem of increasing the rate and/or speed of migration of these cells onto the inner surface, as indicated at column 2, lines 18 to 22 and at line 57 to column 3, line 5 of the patent specification.

For the assessment of the requirements of Article 83 EPC it is not necessary for the Board to determine whether a desired effect, i.e. in the present case the promotion of migration of endothelial cells, has actually been obtained. It is also not the function of the Board to verify if an invention works properly. The disclosure is not required to comprise an explanation of how the desired effect is actually obtained, i.e. an indication of the underlying mechanisms. An invention is in principle sufficiently disclosed if at least one way is clearly indicated enabling the person skilled in the art to carry out the invention, and if the disclosure comprises the necessary technical information that permits the intended result to be achieved at least in some realistic cases (T 487/91, point 5 of the reasons). It should at least be plausible from the disclosure that its teaching does

indeed solve the problem it purports to solve (T 1329/04, point 12 of the reasons). In the Board's view, this is the case in the situation under consideration here. As convincingly explained by one of the inventors, Mr. J.C. Palmaz, it is perfectly plausible that the edges of a groove influence the otherwise zig-zag type of migration of the endothelial cells on a flat surface such that they are guided by the edges of the groove to follow these edges. Their average velocity vector component along the groove thus increases and their migration rate hence becomes accelerated or "promoted" compared to that on a flat surface. All of the grooves depicted in the drawings clearly exhibit edges, and it is not necessary that the term "edge" as such and the resulting effect of guidance be explicitly mentioned or further described in the patent in order to enable the skilled person to carry out the invention as claimed.

The reference to construing the term "groove", inter alia, as a "rounded indentation" in column 6, lines 7 to 10 of the specification is to be understood as relating to the U-shaped configuration of the groove shown in Figure 10 which also has edges, thus being in line with the explanation given above. The fact that in paragraphs [0009] and [0022] the expression "It is believed that ..." is used with respect to the property of the groove increasing the rate of migration represents the understanding of the authors, but does not imply a lack of sufficiency of disclosure.

In document D5 (page 157, right column, penultimate paragraph) one of the inventors of the patent in suit (J.C. Palmaz) stated that introducing texture on a

stent surface may have a beneficial effect on migration, but referred to this effect as a hypothesis which "has not yet been explored". However, such a general and open statement does not mean that this effect does not exist or is impossible to achieve. It is per se not suited to raise serious doubts with regard to the sufficiency of the disclosure of the patent in suit. Moreover, the symposium where the respective presentation was made took place from 15 to 17 October 1997, i.e. several weeks before the priority date of the patent in suit. At least within this period, it is quite possible that the unexplored hypothesis was actually verified. Furthermore, a researcher familiar with the patenting system, like the above-mentioned co-inventor, is unlikely to take the risk of disclosing the details of a potentially patentable invention at a research conference before protecting it by filing a patent application.

In document D9 it is stated that grooves having a depth of 0.5 microns were found to have no effect on cell proliferation (see summary of D9). However, this result relates to the proliferation of rat dermal fibroblasts, which are quite different from endothelial cells, which have the capability of forming monolayers. Moreover, these studies were performed on silicon substrates (see page 1094, left column, penultimate paragraph), a material not normally used on stent surfaces. Accordingly, the teaching of this document does not cast any doubt on the sufficiency of the disclosure of the patent in suit. The introductory statement at page 1093, right column, penultimate paragraph, that the fundamental mechanisms of cell control by guidance in response to surface topography were still unknown

is, like the sentence referred to in D5, very general and does not call into question the effect as such. The same applies to the statement on page 1094, left column, second paragraph, where the influence of micro-geometrical surface patterns on cellular behaviour is referred to as a "hypothesis".

If, in opposition appeal proceedings, the parties make contrary assertions regarding facts considered an obstacle to patentability, as in the present case, the patentee is given the benefit of the doubt, and the burden of proof lies primarily with the opponent (cf. Case Law of the Boards of Appeal of the EPO, 6th edition 2010, VI.H.5.1.1). The argument that routine in-vitro screening studies would not be sufficient for determining whether the grooves promote endothelialisation, which could only be established by means of in-vivo clinical trials representing an undue burden on the opponent, is not accepted by the Board. The decision T 63/06 cited by the opponent-appellant II in this respect is not applicable to the situation under consideration here since, as indicated above, the patentee-appellant I has in fact presented plausible arguments on how the grooves promote endothelialisation, whereas the opponent-appellant II has failed to present convincing counter-arguments or evidence raising serious doubts with respect to workability. Under these circumstances it is not justified to shift the burden of proof to the patentee. The evidence provided by the opponent-appellant II (mainly based on D5 and D9) is not sufficient to call into question the sufficiency of the present disclosure. Such an objection is in principle justified only if there are serious doubts substantiated by

verifiable facts (cf. Case Law of the Boards of Appeal of the EPO, 6th edition 2010, VI.H.5.1.1). Neither condition is fulfilled in the present case.

Accordingly, the invention as described in the present patent and defined in the claims according to the various requests is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art as required by Article 83 EPC.

5. Novelty

5.1 Main request

Document D1 is state of the art relevant under Article 54(3) EPC. It describes (see page 4, second paragraph and page 10, line 9, to page 12, line 13) the manufacturing of a stent by coating or dusting a soluble particulate material such as sodium bicarbonate onto a mandrel, then coating an insoluble film-forming material, for instance a polymer, thereover and subsequently curing the film-forming material on the mandrel to form the body of the stent, and finally dissolving the soluble particles after removal from the mandrel, resulting in the formation of recesses in the inner surface of the stent (page 3, lines 12 to 14). The size of the recesses is controlled by the size of the particulate material (page 9, lines 2 to 5).

Accordingly D1 discloses an intravascular stent having an outer surface and an inner surface and comprising at least one groove disposed in the inner surface of the stent, wherein the at least one groove has a width, a length having a dimension greater than the width, and a

depth less than the distance between the inner surface and the outer surface of the stent. Since according to page 7, line 11, the particulate material may consist of fibres, which generally have a length greater than their width or diameter, the resulting recesses will be elongate and thus take the shape of grooves, each having a length greater than its width. Moreover, as stated at page 7, lines 15 to 18, only some of the recesses form passageways through the stent. Consequently, there are necessarily also recesses or grooves in the inner surfaces which do not form such passageways and which therefore have a depth less than the distance between the inner surface and the outer surface of the stent. The thus formed "at least one groove" comprises edges, thereby inherently "promoting migration of endothelial cells onto the inner surface of the stent when the stent is implanted", as explained above under point 4. Accordingly, this functional feature of claim 1 is also disclosed, implicitly. The fact that D1 also teaches cellular migration into and through the passageways (page 3, lines 24 to 27; page 7, lines 19 to 20; page 18, lines 9 to 11) does not change this finding.

The grooves or recesses disclosed in D1 may be arranged in an irregular pattern, as argued by the patentee-appellant I, but claim 1 does not define any particular orientation of the grooves. The fact that some of the fibres may overlap and that some of the inner recesses in D1 communicate with the outer recesses, thus creating passageways through the polymeric film, is not relevant for the comparison with the wording of claim 1. The recesses or grooves of D1 may have variable shapes and variable depths, but such

variations are well within the scope of claim 1 and are more specifically claimed in dependent claims 4 and 7 as granted.

Accordingly, the subject-matter of claim 1 of the main request is known from D1 and therefore not new under Article 54(3) EPC.

5.2 Second auxiliary request

Document D2 is also relevant under Article 54(3) EPC. It discloses an intravascular stent formed of a sheet 11 rolled into a tubular body 13 of multiple overlapping layers of sheet 11 (Figure 4). The stent has an outer surface (of the outermost layer) and an inner surface (of the innermost layer). The inner surface comprises elongated perforations or slots 28 which partially overlap with those in the other layers, thus forming through-openings or "net apertures" 60 extending completely through the side wall of the stent (Figure 5). The non-overlapping portions of these perforations in the innermost layer form grooves having a bottom. As stated in lines 14 to 17 of page 6 of D2, the layers comprising the perforations bear against one another under spring force. This implies that there are practically no spaces left between the layers, whatever the configuration of the vessel into which the stent is inserted. Accordingly, the non-overlapping portions of the slots 28 in the innermost layer forming the grooves have a depth less than the distance between the inner surface and the outer surface of the stent. The diameter of the net apertures corresponds roughly to the width of the slots (page 10, lines 33 to 36). As convincingly demonstrated by the opponent-appellant II,

a more exact calculation taking into account the angles between the directions of the perforation zones as described at page 7, lines 25 to 29, yields a slot or groove width $W = D \cdot \cos 45°$, with D denoting the maximum diameter of the net apertures. With a diameter D of less than about 0.05 mm or about 0.001 inches (about 25 microns) as disclosed at page 11, lines 2 to 3 and 6 to 8 respectively, the resulting width W is less than about 25 microns or about 18 microns, respectively, these values falling well within the claimed range of 2 to 40 microns and thus taking away its novelty. Since the slots or perforations are elongate, the grooves have a length greater than their width. The grooves necessarily comprise edges (see Figure 5), thus inherently "promoting migration of endothelial cells onto the inner surface of the stent when the stent is implanted", as explained above under point 4. Accordingly, this feature of claim 1 is also disclosed implicitly. The fact that D2 also suggests that the net apertures facilitate endothelial cell growth through the side wall of the stent (page 10, lines 28 to 30) does not change this finding. Endothelial cell growth onto and along the surfaces of the stent is described to occur as well, at least to a certain extent (page 11, lines 11 to 14).

The argument of the patentee-appellant I that spaces exist between successive layers of the sheet material (to be seen in Figures 4 and 5), particularly when the stent is implanted into an irregularly shaped, pulsating blood vessel, is speculative and not convincing in view of the above-mentioned statement, at lines 14 to 17 of page 6 of D2, that the layers bear against one another under spring force. Such spaces

would also counteract the desired effect of the net apertures being small enough to prevent substantial blood loss therethrough (page 10, lines 28 to 30).

Accordingly, the subject-matter of claim 1 of the second auxiliary request is known from D2 and therefore not new under Article 54(3) EPC.

5.3 Third auxiliary request

5.3.1 Document D1 discloses various values of the diameters of the particulate material and the recesses resulting therefrom (page 10, lines 27 to 29 and page 7, lines 6 to 9, respectively). However, with respect to the dimensions of the fibres (which are only briefly mentioned at page 7, line 11) this document is entirely silent. Since, as explained above (point 5.1), only the elongate recesses resulting from the fibres can be regarded as "grooves", no absolute dimensions can be derived directly and unambiguously from D1 with respect to the grooves. The photographs of the inner surface (in particular Figure 7) do not reveal any information with respect to the depth of the recesses. Accordingly, claims 1 and 22 of the third auxiliary request are distinguished from D1 by the depth of the groove being within a range of one-half to ten microns.

5.3.2 Document D2 discloses, at page 13, lines 1 to 2, various values of the sheet thickness. Based on the analysis presented above (point 5.2), the thickness of the sheet is equivalent to the depth of the grooves formed in the innermost layer of the sheet 11. A sheet thickness "as low as 0.001 inches" corresponds to about 38 microns which clearly falls outside the claimed

range of 0.5 to 10 microns. It is further mentioned that the thickness may be "preferably as low as 0.0005 inches or less". The stated value corresponds to about 12.7 microns which also falls outside the claimed range. The term "as low as" indicates that this is in fact the lowest value actually considered in D2, and the expression "or less" does not comprise any concrete and unambiguous teaching that could anticipate the claimed range.

5.3.3 It follows that the subject-matter of claims 1 and 22 of the third auxiliary request is new under Article 54(3) EPC vis-à-vis document D1 as well as D2.

5.3.4 Document D11 discloses a stent (column 11, line 37) made from an extruded tubing of stretched porous PTFE having a microstructure composed of nodes of interconnected fibres (column 12, lines 42 to 56). This structure, however, fails to exhibit any kind of "groove". For this reason alone, the subject-matter of claims 1 and 22 of third auxiliary request is new vis-à-vis document D11. As none of the other prior-art documents on file discloses in combination all the features of these claims, their subject-matter is new (Article 54(1) and (2) EPC).

6. Inventive step - third auxiliary request

6.1 Document D3 as closest prior art discloses an intravascular stent 35 having an outer surface and an inner surface (Figure 7). The stent comprises at least one groove 48 disposed in the inner surface of the stent, wherein the at least one groove has a width and a length having a dimension greater than the width

(Figure 8). The groove 48 can interlock with groove 49 so that the stent has a fixed expanded diameter (column 4, lines 40 to 43). The wall of the stent comprises openings promoting epithelialisation (column 4, lines 12 to 14 and bottom of column 3).

Claims 1 and 22 are distinguished over D3 by the depth of the groove being within a range of one-half to ten microns (D3 is silent with respect to the dimensions of the groove 48) and by the functional feature of the groove promoting migration of endothelial cells onto the inner surface of the stent when the stent is implanted (the groove 48 in D3 has an entirely different function and its rounded and smooth contours are not suited to achieve the desired effect of accelerating the migration of the endothelial cells).

The objective technical problem to be solved by these distinguishing features is to protect more effectively the inner surface of the stent from thrombus deposition and restenosis resulting therefrom (cf. column 2, line 45 to column 3, line 1 of the patent specification).

The inventive solution resides in the provision of grooves with the configuration as claimed on the inner surface of the stent. It is based on the recognition that such grooves accelerate the speed and rate of migration of endothelial cells (cf. point 4 above) and thus lead to a more rapid endothelialisation as compared to the known electropolished surfaces having an extremely smooth surface finish.

D3 itself gives no hint towards re-designing the at least one groove to exhibit the features as claimed. The wall 40 of the stent (and thus its inner surface) is described as "generally smooth" (column 4, lines 12 to 14). Moreover, a groove 48 with a depth in the claimed range would no longer be able to perform its intended interlocking function.

D10 is a review of various studies investigating the role of the morphology of different substrate surfaces on the spreading and migration of various types of biological cells (see in particular Table I on pages 766 and 767). Endothelial cells are not addressed at all. Only rows 11 to 15 of Table I refer to Ti-coated substrates that might be comparable to the surfaces of stents made from titanium. Rows 12 to 15 refer to grooves having depth (d) ranges (see column 3 of Table I) overlapping with the claimed range. Among those, rows 12 and 13 state that migration has been studied (see column 5), without however indicating any results, i.e. without giving an indication that migration was actually promoted or accelerated. With respect to the underlying studies by Brunette it is merely stated (see D10, page 767, left column, last eight lines from the bottom) that groove depth had a relatively small effect on the degree of cell orientation. Finally, the types of cells studied were porcine gingival fibroblasts and porcine periodontal epithelial cells, respectively, which are both quite different from vascular endothelial cells (which are capable of forming monolayers). The reference of the opponent-appellant II to D11, column 4, lines 31 to 32, possibly suggesting that endothelial cells might be considered as a subclass of epithelial cells, is not an indication that

migration studies obtained with porcine periodontal epithelial cells permit any conclusions with regard to the behaviour of vascular endothelial cells under the same conditions. The general indications in D10 (page 765, left column, penultimate paragraph, and page 769, right column, penultimate paragraph) that the surface morphology should be in the same order of magnitude as a cell in order for its growth, function or adhesion to be affected gives no hint towards the provision of grooves of the specific depth range as claimed for promoting migration of endothelial cells onto the inner surface of a stent. The same applies to the statement in the summary of D10 at page 764 that multiple parallel grooves can enhance cell adhesion (a phenomenon not to be confused with migration) by confining the cells in grooves. Accordingly, the subject-matter of claims 1 and 22 is not rendered obvious by D3 in view of D10 and D11.

6.2 D4 as a starting point discloses a blood vessel replacement prosthesis rather than a stent. The inner surface comprises a plurality of substantially cylindrical recesses 16 having a diameter on the order of 10 microns (column 2, lines 49 to 50) and a depth about two to three times as much (column 2, lines 56 to 57). These recesses are to promote the build-up and firm attachment of a neointima lining to the inner surface (column 1, lines 52 to 57).

Accordingly, claims 1 and 22 are distinguished over D4 by at least one groove disposed in the inner surface of the stent, wherein the at least one groove has a width, a length having a dimension greater than the width, and a depth within a range of one-half to ten microns, the

depth being less than the distance between the inner surface and the outer surface of the stent, the at least one groove promoting migration of endothelial cells onto the inner surface of the stent when the stent is implanted.

The objective technical problem to be solved by these distinguishing features is again to protect more effectively the inner surface of the stent from thrombus deposition (cf. point 6.1 above).

D4 itself gives no hint to deviate from the cylindrical recesses and to modify them into grooves, and to reduce their depth, which is at least about twice as much as the upper value of the claimed depth range. On the contrary, both modifications would be likely to counteract the desired function of the recesses, namely the secure anchoring of blood particles to form a neointima lining which will not break free (column 5, lines 52 to 57). Promoting the migration of endothelial cells is not addressed at all in D4.

The combination of D4 with document D10 does not render the claimed subject-matter obvious, for the same reasons as already indicated above under point 6.1.

6.3 It follows that the subject-matter of claims 1 and 22 of the third auxiliary request involves an inventive step within the meaning of Article 56 EPC.

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 the following documents:

   Claims: Nos. 1 to 42 of the third auxiliary request filed with the patentee's letter of 1 December 2008;

   Description: columns 1 to 8 as maintained by the department of first instance;

   Drawings: Figures 1 to 16 as granted.

The Registrar: The Chairman:

D. Sauter M. Noël